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Identification and Listing of Hazardous Waste Under RCRA (Resource Conservation and Recovery Act), Subtitle C, Section 3001. EP Toxicity Characteristic (40 CFR 261.24)

(U.S.) Environmental Protection Agency
Washington, DC

May 80

U.S. Department of Commerce
National Technical Information Service
NTIS

BACKGROUND DOCUMENT

IDENTIFICATION AND LISTING OF HAZARDOUS WASTE
UNDER RCRA, SUBTITLE C, SECTION 3001

EP Toxicity Characteristic
(40 CFR 261.24)

This document (ms. 1941.26) provides background information
and support for EPA's hazardous waste regulations

U.S. ENVIRONMENTAL PROTECTION AGENCY
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This document is one of a series providing support for regulations issued by the U.S. Environmental Protection Agency (EPA) under Subtitle C of the Resource Conservation and Recovery Act (RCRA). The regulations represent the initial effort for nationwide control of hazardous waste from point of generation, through transportation, treatment, and storage, to point of ultimate disposal.

This document explains how EPA identified extraction procedure toxicity as a hazardous characteristic.

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I. Proposed Regulation

(1) Definition

A solid waste is a hazardous waste if, according to the methods specified in paragraph (2), the extract obtained from applying the Extraction Procedure (EP) cited below to a representative sample of the waste has concentrations of a contaminant that exceeds any of the following values:

Contaminant:	Extract level milligrams per liter
Arsenic	0.50
Barium	10.0
Cadmium	0.10
Chromium	0.50
Lead	0.50
Mercury	0.02
Selenium	0.10
Silver	0.50
Endrin (1,2,3,4,10,10-hexacloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1, 4-endo, endo-5,8-dimethanonaphthalene)	0.002
Lindane (1,2,3,4,5,6 hexachlorocyclo hexane gamma isomer)	0.040
Methoxychlor (1,1,1-Trichloroethane) 2,2-bis (p-methoxypheny)	1.0
Toxaphene (C H CL - technical chlorinated camphene, 67-69 percent cholrine)	0.050
2,4-D, (2,4-Dichlorophenoxyacetic acid	1.0
2,4,5-TP (Silvex) (2,4,5-Trichlorophenoxypropionic acid	0.10

NOTE: - Extract levels specified for the above substances equal ten times the EPA National Interim Primary Drinking Water Standards for these substances. These standards are being revised. Extract levels specified above will be changed to reflect revisions to these standards. Also, EPA is considering use of the Water Quality Criteria under the Clean Water Act as a basis for setting extract levels, in addition to the EPA National Interim Primary Drinking Water Standards.

(2) Identification Method

(i) Extraction procedure. (2) Identification method. (A) Take a representative sample (minimum size 100 gms) of the waste to be tested and separate it into its component phases using either the filtration method or the centrifugation method described in this section.

Reserve the liquid fraction under refrigeration at 1-5°C (34-41°F) for use as described in paragraph (F) of this section.

(1) Filtration Method.

Equipment: Millipore YY22 142 30 filter holder (Millipore Corp., Beford, MA, 01730) equipped with an XX42 142 08 necessary 1.5 liter reservoir, or Nuclepore Corp., Pleasanton, CA 94566) equipped with a 1.5 liter reservoir, or equivalent filter holder.

Procedure: 1. Using the filter holder place a 0.45 micron filter membrane (Millipore type HAWP142, Nuclepore type 112007, or equivalent) on the support screen. On top of the membrane (upstream) place a prefilter (Millipore AP25124, Nuclepore P040, or equivalent). Secure filter holder as directed in manufacturer's instructions.

2. Fill the reservoir with the sample to be separated, pressurize to no more than 75 psi (7 kg/cm^2), and filter until no significant amount of fluid (o.5 ml) is released during a 30 minute period.

3. After liquid flow stops, depressurize and open the top of the reservoir, invert the filter unit, replace filter pads as in step 1. above, and resume filtering. Save pads for later use. Repeat this step until no more fluid can be removed from the waste at a pressure of 75 psi (7kg/cm2).

4. Take the solid material, and any pads used in filtration, and extract as described in paragraph (B). Subtract tare weights of filter pads in calculating the amount of solid material.

(2) Centrifugation Method

Equipment: Centrifuge (e.g. Damon-IEC catalog no. 7165, Damon-IEC Corp., Needham Heights, MA, or equivalent) equipped with a rotor for 600 ml to 1 liter containers (Damon-IEC catalog no. 976, or equivalent). For flammable material containing wastes, explosion proof equipment is recommended.

Procedure 1. Centrifuge sample for 30 minutes at 2300 rpm. Hold temperature at 20-40°C (68-104°F).

2. Using a ruler, measure the size of the liquid and solid layers, to the nearest mm (0.40 inch). Calcuate the liquid to solid ratio.

3. Repeat 1 and 2 above until the liquid: solid ratio calculated after two consecutive 30 minute centrifugations is within 3%.

4. Decant or siphon off the layers and extract the solid as described in paragraph B.

(8)

(B) Take the solid portion obtained in paragraph (i), and prepare it for extraction by either grinding it to pass through 9.5 mm (3/8) standard sieve or by subjecting it to the following structural integrity procedure.

STRUCTURAL INTEGRITY PROCEDURE

Equipment: Compaction tester having a 1.25 inch diameter hammer weighing 0.73 lbs. and having a free fall of 6 inches (Figure 1) (one suitable device is the Associated Design and Manufacturing Company, Alexdria, Va. 22314, catalog no. 125).

Procedure: 1. Fill the sample holder with the material to be tested. If the waste sample is a monolithic block, then cut out a representive sample from the block having the dimensions of a 1.3" dia. x 2.8" cylinder.

2. Place the sample holder into the Compaction Tester and apply 15 hammer blows to the sample.

3. Remove the now compacted sample holder and transfer it do the extraction apparatus for extraction.

(C) Take the solid material from paragraph (B), weight it and place it in an extractor. A suitable extractor will not only prevent stratification of sample and extraction fluid but also insure that all sample surfaces are continuously brought into contact with well mixed extraction fluid. When oprated at greater than or equal to 40 rpm, one suitable device is shown in figure 2 and available as Part No. 3736 produced by Associated Design and Mfg. Co., Alexandria, Va. 22314)

(D) Add to the extractor a weight of deionized water equal to 16 times the weight of solid material added to the extractor. This includes any water used in transferring the solid material to the extractor.

(E) Begin agitation and adjust the pH of the solution to 5.0+ 0.2 using 0.5N acetic acid. Hold the pH at 5.0+0.2 and continue agitation for 24+0.5 hours. If more than 4 ml of acid for each gm of solid is required to hold the pH at 5, then once 4 ml of acid per gm has been added, complete the 24 hour extraction without adding any additional acid. Maintain the extractant at 20-40°C (68-104°F) during extraction. It is recommended that a device such as the Type 45-A pH Controller manufactured by Chemtrix, Inc. Hillsboro, OR 97123, or equivalent, be used for controlling pH. If such a device is not available then the following manual procedure can be employed.

MANUAL pH ADJUSTMENT

1. Calibrate pH meter in accordance with manufacturer's specifications.

2. Add 0.5N acetic acid and adjust pH of solution to 5.0 + 0.2. If more than 4 ml of solution to 5.0 + 0.2. If more than 4 ml of acid for each gm of solid is required to hold the pH at 5, then once 4 ml of acid per gm has been added complete the 24 hour extraction without adding any additional acid. Maintain the extractant at 20-40°c (68-104° F) during extraction.

3. Manually adjust pH of solution at 15, 30, and 60 minute intervals moving to the next longer interval if the pH did not have to be adjusted more than 0.5 pH units since the previous adjustment.

4. Continue adjustment procedure for a period of not less than 6 hours.

5. Final pH after a 24 hour period must be within the range 4.9-5.2; unless 4 ml of acid per gram of solid has already been added.

6. If the conditions of 5 are not met, continue pH adjustment at approximately one hour intervals for a period of not less than 4 hours.

(F) At the end of the 24 hour extraction priod, separate the material in the extractor into solid and liquid phases as in paragraph (A). Adjust the volume of the resulting liquid phase with deionized water so that its volume is 20 times that occupied by a quantity of water at 4° C equal in weight to the initial quantity of solid material charged to the extractor (e.g., for an initial weight of 1 gm, dilute to 20 ml). Combine this solution with the original liquid phase from paragraph (A). This combined liquid, and any precipitate which may later form, is the Extraction Procedure Extract.

(ii) Analysis - Analyses conducted to determine conformance with Section 250.13(b)(1) shall be made in accordance with the following or equivalent methods:

(A) Arsenic - Atomic Absorption Method, "Methods for Chemical Analysis of Water and Wastes," pp. 95-96, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(B) Barium - Atomic Absorption Method, "Standard Methods for the Examination of Water and Wastewater" latest edition, or Methods for Chemical Analysis of Water and Wastes, "pp. 97-98, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(C) Cadmium - Atomic Absorption Method, "Standard Methods for the Examination of Water and Wastewater", latest edition, or "Methods for Chemical Analysis of Water and Wastes". pp. 101-103, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(D) Chromium - Atomic Absorption Method, "Standard Methods for the Examination of Water and Wastewater", latest edition, or "Methods for Chemical Analysis of Water and Wastes", pp. 112-112, Environmental Protection Agency, Office of Technology Transter, Washington, D. C. 20460, 1974.

(E) Lead - Atomic Absorption Method, "Standard Methods for the Examinations of Water and Wastewater", latest edition, or "Methods for Chemical Analysis of Water and Wastes", pp. 112-113, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(F) Mercury - Flameless Atomic Absorption Method, "Methods for Chemical Analysis of Water and Wastes," pp. 118-126,, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460.

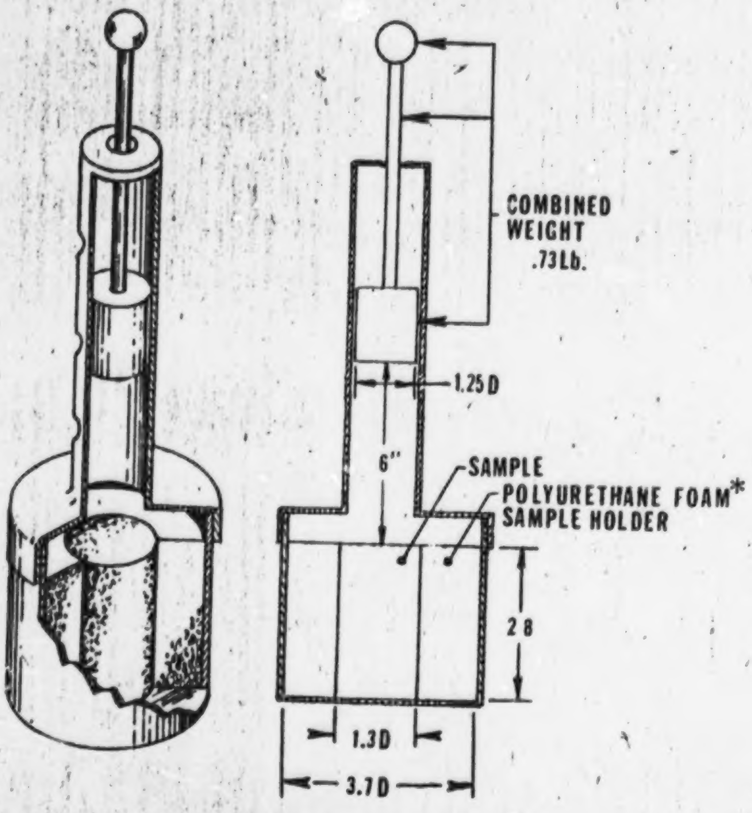
(G) Selenium - Atomic Absorption Method, "Methods for Chemical analysis of Water and Wastes," p. 145, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(H) Silver - Atomic Absorption Method, "Standard Method for the Examination of Water and Wastewater," latest edition, or Methods for Chemical Analysis of Water and Wastes", p. 146, Environmental Protection Agency, Office of Technology Transfer, Washington, D. C. 20460, 1974.

(I) Endrin, Lindane, Methoxychlor, or Toxaphene - as desribed in "Method for Organochlorine Pesticides in Industrial Effluents", MDOARI, Environmental Protection Agency, Cincinnati, Ohio, November 28, 1973.

(J) 2,4-D and 2,4,5-TP Silver-as described in "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," MDQARI, Environmental Protection Agency, Cincinnati, Ohio, November 28, 1973.

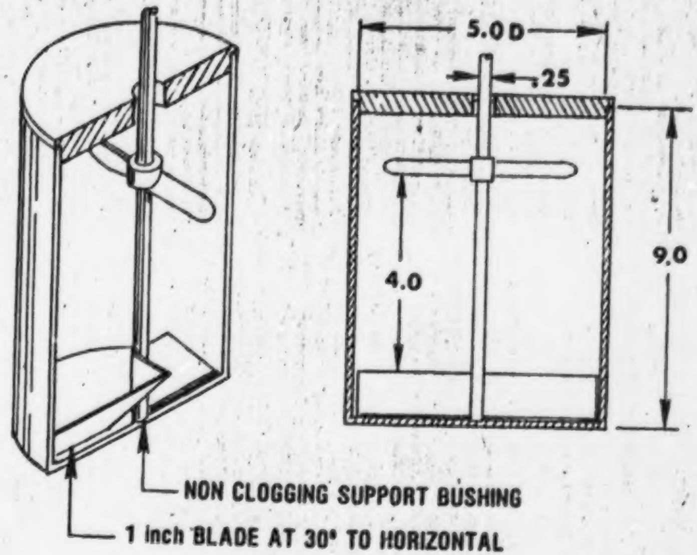
Figure 1


COMBINED WEIGHT .73Lb.
1.25 D
6"
SAMPLE
POLYURETHANE FOAM*
SAMPLE HOLDER
2 8
1.3 D
3.7 D

COMPACTION TESTER

*Polyurethane foam shall conform to requirements for Grade 21, performance Grade AD or BD, established in ASTM Standard D3453.

Figure 2


5.0 D
.25
9.0
4.0
NON CLOGGING SUPPORT BUSHING
1 inch BLADE AT 30° TO HORIZONTAL

EXTRACTOR

II. DEVELOPMENT AND RATIONALE FOR THE CHARACTERISTIC

A. NEED FOR A TOXICITY CHARACTERISTIC

Subtitle C of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) creates a regulatory framework for controlling the management of hazardous waste. Section 3001 of RCRA requires the U.S. Environmental Protection Agency (referred to herein as the Agency) to identify the characteristics of and to list hazardous wastes. Those wastes so identified are then included in the waste management control system set forth in Sections 3002 to 3006 and 3010 of RCRA.

This Background Document describes the process by which the Agency identified and defined one such characteristic, the "Extraction Procedure Toxicity Characteristic", and presents the rationale, assumptions, models, and scientific studies employed in defining the characteristic. This document also discusses the comments received on the proposed characteristic and the changes made in response to those comments.* For clarity the name for this characteristic has been changed from the proposed "Toxicity Characteristic to the Extraction Procedure Toxicity Characteristic in the final regulations.

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*The distinction between a waste which is hazardous because it possesses the *characteristic* of toxicity, and a waste which is listed as hazardous because it meets the *criteria* of toxicity, is explained in detail in the background document on Identification and Listing of Hazardous Waste.

B. NATURE OF TOXICITY REGULATED UNDER THE SUBTITLE C REGULATIONS

Section 1004(5) of RCRA defines a hazardous waste as one that may:

(A) cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or

(B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

The usual conception of "toxicity" certainly meets this standard.* Furthermore, section 3001(a) requires that toxicity be taken into account in determining which wastes are hazardous.

As used in these regulations, "toxicity" includes a wide range of hazardous effects. Acute toxicity upon exposure is one such effect. Toxicity is also used to encompass the specific properties of aquatic and mammalian chronic toxicity, carcinogenicity, mutagenicity, teratogenicity, and phytotoxicity. Another property of toxicity deemed of regulatory significance is the potential to bioaccumulate in animal tissue (see section 3001(a)). The following properties of toxicity are of particular regulatory concern:

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*Webster's New Collegiate Dictionary, for example, indicates that toxic is synonomous with poisonous.

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- serious harm to humans resulting from long term subacute exposure to chemicals released from the waste (i.e., death, incapacitation, cancer, birth defects, damage to future generations through changes in the gene pool);
- serious diminution of fishing resources resulting from contamination of surface water bodies; and
- serious harm to agricultural resources resulting from use of water contaminated by waste management practices for irrigation.

These choices are easily justifiable. In addition to the obvious need to regulate wastes which may result in death or incapacitation, wastes posing a threat of carcinogenicity are of special concern. Chemicals present in the environment, combined with dietary and societal influences, have been implicated in the high incidence of cancer in humans. In order to lessen human exposures to carcinogens, it is necessary to handle and dispose of wastes containing significant quantities of carcinogens in a manner appropriate for hazardous materials.

An additional danger from which society requires stringent protection is exposure to chemicals capable of damaging genetic material (i.e., mutagens). As a recent review in the American Chemical Society's Chemical and Engineering News stated:

> The relationship between mutagenicity and carcinogenicity debated by many, up to 90% of the chemicals so far tested and identified as mutagens in one or more short term tests are carcinogens as well.
>
> Cancer is only one consequence of genetic mutation, but the tragedy of its human dimension attracts public attention. Another potential serious threat from mutagens may lie in store for future generations:

(15)

> the insidious accumulation of subtle, irreversible mutations in the gene pool conceivably could have horrific consequences for the human race. By the time the effects of such mutations become apparant it'll be too late. (1)

Protection of the unborn fetus is another important goal of the hazardous waste program under RCRA. In order to lessen the likelihood of birth defects occurring as a consequence of improper management of waste materials, it is important to identify and regulate management of wastes containing teratogenic substances.

Protection of fishing resources is also an important goal of the hazardous waste program. Fishing is both a major source of income and food to many people and serves an important recreational purpose as well.

Congress cited several instances of fish kills in describing the types of substantial harm caused by hazardous waste mismanagement (2), indicating an intent to protect this resource from improper hazardous waste management. Furthermore, the Act requires the Agency to consider and procect not only "human health" but "the environment" in determining which wastes are hazardous (section 1004(5)).

Serious harm to fishing resources due to mismanagement of wastes can occur in two important ways. Discharge of toxic chemicals to waterways can result in the immediate death of large numbers of fish. This has occured many times during the past decade as a consequence, most notably, of transportation accidents. A second, more insidious threat,

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is posed by long term, low level discharge of chemicals to surface waters via groundwater transport. These chronic exposures can interfere with growth and reproduction, as well as cause death, and can lead to long term disappearence of aquatic resources of a water body. The Agency believes it is important to regulate wastes posing such a risk in order to safeguard this important national resource.

Protection of agricultural resources is an additional goal of the hazardous waste program, inasmuch as large amounts of ground and surface water are used in the United States for crop irrigation. According to the U.S. Geologic Survey,

> "The quantity of water withdrawn for irrigation in the United States, Puerto Rico, and the Virgin Islands in 1975 was estimated at 160 million acre-feet... This was an average rate of 140 billion gallons per day, and the water was used on approximately 54 million acres of farmland. This represents an increase in water use of about 10.9 percent over the 1970 estimate and an increase in acreage of about 9.4 percent."(3)

Plants often absorb harmful materials from their environment. It is therefore extremely important, given the critical importance of agriculture, that the sources of water available for irrigation be kept safe for this use. Furthermore, human exposure to waste contaminants may result from ingestion of food-chain crops exposed to contaminated water. Again, the threat to human health and the environment is plain, and warrants regulatory protection.

C. SCOPE OF THE TOXICITY CHARACTERISTIC

After identifying the various aspects of toxicity that are of concern, the Agency attempted to develop a definition for the "Extraction Procedure Toxicity Characteristic" which would encompass all of these aspects. Detailed discussions of the approach employed in attempting to develop such a broad characteristic have been detailed previously in materials made available to the public. (4,5,6,7)

However, the Agency was unsuccessful in developing such a definition. The EP Toxicity Characteristic promulgated today is limited to wastes which present a hazard to human health due to propensity to leach significant concentrations of those toxicants for which drinking water thresholds have been established. It should be noted, however, that although the EP Toxicity Characteristic regulates only those wastes containing toxic constituents for which National Interim Primary Drinking Water Standards (8) have been established, other wastes may still be regulated as toxic via the listing mechanisms under §§261.31 through 261.33 of the regulations.

(1) Aspects of Toxicity Outside the Scope of EP Toxicity Characteristic

(a) Chronic Toxicity of Wastes Containing Contaminants Other Than Those Included in the National Interim Primary Drinking Water Standards

In addition to the 14 substances for which National Interim Primary Drinking Water Standards have been established, there exist thousands of other chemicals which possess a significant toxicity. The Agency has wrestled unsuccessfully with the problem of setting definitional thresholds for these diverse potential toxicants. While one possible approach was outlined in the proposed Part 250.15 delisting requirements, adoption of this approach was found to suffer from a number of problems, principally the lack of a recognized means of setting a threshold to measure these compounds' chronic toxicity. In addition, there is believed to be insufficient laboratory capacity to analyze generators' wastes or waste extracts for the thousands of toxic species involved. At the present time, therefore, only wastes containing the drinking water contaminants are within the scope of the characteristic.

(b) Carcinogenicity

A number of groups are active in identifying chemicals which are carcinogenic to humans. EPA's Cancer Assessment Group has taken the lead for the Agency in evaluating available information in order to determine which chemicals show substantial evidence of carcinogenicity.

The Cancer Assessment Group has evaluated the available information on a large number of such chemicals. They have concluded (10) that for approximately 150 compounds the information was sufficient for the compounds to be considered suspect human carcinogens.

This list was not made part of the self-regulating EP Toxicity Characteristic because of:

a. the lack of laboratory capacity to analyze all wastes for the presence and concentration of these compounds, and

b. the absence of the necessary dose-response and mobility relationships with which to derive general waste threshold levels which would withstand scientific challenge.

In addition to doing reasearch on methodology for specific compound identification and quantification, the Agency is conducting research to develop rapid, inexpensive biological screening methods to identify wastes containing carcinogenic materials. However, until such time as these methods are available, the Agency will identify specific carcinogen containing wastes through the listing mechanism.

c. Mutagenicity

There are a variety of mechanisms by which chemicals can act to cause damage to DNA. A program of waste control aimed at identifying and eliminating human exposure to such materials requires rapid, inexpensive procedures to pinpoint dangerous materials. In response to this problem, a number of rapid and potentially inexpensive bacterial and in vitro cellular tests have been developed. These tests are designed to identify mutagenic substances by detecting genetic damage in the test species. Because of the variety of types of DNA damage that are possible, no one test is sufficient to identify all mutagenic substances.

Although test procedures of this type are in general use for identifying potentially hazardous chemicals, the Agency has decided not to require their general use by the regulated community for two reasons:

(1) Research to date has not been sufficient to develop and validate experimental methodologies

for using these tests to evaluate the potential hazard posed by wastes;

(2) There is significant scientific uncertainty as to the degree to which such screening test results correlate with human toxicity.

There are currently a number of large scale programs being conducted to determine the applicability and validity of short term mutagenicity test systems. Foremost among these are the International Program for the Evaluation of Short-Term Tests for Carcinogenicity, the Genetox Program and the National Toxicology Program. The "International Program" is approximately three years old, while the other two programs have been underway for about two years and one year respectively. Detailed conclusions relative to the utility of short-term tests for mutagenicity are not yet available.

The Agency therefore has decided to postpone use of such tests pending the results of further studies. Wastes found to contain compounds posing a mutagenic threat to humans or the environment will be regulated through the listing mechanism.

d. Teratogenicity

There are at present no suitable testing methods capable of identifying teratogenic wastes. Consequently, in order to lessen the likelihood of birth defects occurring as a consequence of improper management of waste materials, the Agency will rely in the listing mechanism to reach such wastes.

e. Chronic Toxicity to Fish

The Agency encountered two problems in developing a toxicity test protocol for protection of fisheries resources. The first of these problems was the selection and development of a scenario to relate waste management to contamination of surface waters in which fish live. The second problem was in then establishing thresholds to determine what an unacceptable level of surface water contamination would be.

While a possible solution to the first of these problems (i.e., relating disposal to exposoure) was presented in the December 15, 1978 Draft Toxicity Background Document (6), the contamination model did not account for exposure occurring through either direct discharge or surface runoff. In addition to its incompleteness, the model suffered from the fact that the mixing zone dilution was not based on actual environmental data.

The second major problem relates to the unavailability of thresholds analogous to the drinking water standards. The Agency currently has a program underway to develop water quality guidelines. These guidelines will reflect the Agency's best scientific judgment as to maximum levels of toxic species in waters consistent with protection of the aquatic resources. However, until such time as these guidelines are available, the Agency does not believe it is in a position to complete development or propose a toxicity characteristic for protection of fishery resources. Thus, identification of wastes posing a significant hazard to fish will be made using the listing mechanism.

f. Phytotoxicity

Besides not having threshold values to measure chronic exposure levels for fish, the Agency lacks threshold toxic exposure levels for plants as well. Thus, in order to protect against harm to agriculture resources, the listing mechanism will be used to bring phytotoxic wastes into the hazardous waste control system.

D. MAJOR POSTULATES CONTAINED IN THE CHARACTERISTIC

As noted above, the Extraction Procedure Toxicity Characteristic is limited to evaluation of the substantiality of hazard to human health posed by leachable waste constituents for which National Interim Primary Drinking Standards exist. The major postulates underlying the characteristic, and the reasons therefor are set out below.

1. Choice of Groundwater Exposure Pathway

For wastes defined as toxic by Section 1004(5), the hazard posed by a waste is dependent primarily on two factors:

a. the intrinsic toxic properties of the constituents in the waste (e.g., acute toxicity, chronic toxicity, genetic activity, bioaccumulation); and

b. the propensity of the constituents in the waste to migrate from the waste during management and result in environmental exposure.

The first factor, the intrinsic hazard, defines the actual health effect posed by the waste when exposure to the public or environment occurs. For the compounds identified in the characteristic promulgated today, sufficient toxicological information (i.e., National Interim Primary Drinking Water Standards) was available for EPA to determine not only intrinsic toxicity but safe exposure levels as well.

The second factor was not as well defined. That is, no test procedures were available to relate concentrations of toxic species in a waste to migration into the environment during waste management. Therefore, in order to develop the Extraction Procedure Toxicity Characteristic, the Agency found it necessary to develop a procedure to evaluate the propensity of a toxic material present in a waste to enter the environment and result in human exposure.

In considering the various exposure pathways of concern, the Agency concluded (not surprisingly) that the most probable ones were groundwater, surface water, and air. The groundwater pathway is believed to be the most serious for a number of reasons:

(1) Protection of groundwater from leachate contamination was one of Congress' principal objectives in enacting RCRA. (2)

(2) Groundwater serves as a source of drinking water for at least half of the propulation of the United States, and almost one-fifth obtains drinking water directly from groundwater wells. (11)

(3) Once contaminated, groundwater aquifers tend to remain contaminated for extended periods of time since their renewal times are very long.

(4) Groundwater aquifer contamination is difficult to detect, particularly in its early stages. Significant human exposure may thus occur before remedial action can be taken.

(5) Numerous incidents of groundwater contamination resulting from improper waste management have actually occurred.*

2. Choice of Particular Disposal Environment Model

a. Choice of Landfill Disposal

In considering the various forms of industrial waste management likely to occur which would lead to exposure via a

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*The prevalence of the problem of groundwater contamination is illustrated by a 1977 study (12) of 50 land disposal sites that had received industrial wastes. At 13 sites, the study was able to obtain evidence that organic chemicals had migrated from the disposal site to groundwater, and that organic contamination of groundwater had occurred. Similarily, at 30 of the sites, inorganic contaminants were found to have migrated to groundwater. At 26 of these sites, hazardous inorganic constituents in the water at one or more monitoring wells was found to exceed the EPA drinking water limits. This study is but one indication of the potential for groundwater contamination posed by existing waste management. Other damage incidents are collected in open files of the EPA Office of Solid Waste, Hazardous and Industrial Waste Division, and are in the Subtitle C rulemaking record.

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groundwater pathway (e.g., landfilling, land treatment, surface impounding, biological treatment), landfill disposal was believed to offer the greatest potential for mismanagement. The Agency reached this latter conclusion after considering the following factors:

(1) Land disposal of wastes results in the concentration of toxic species into a relatively small area,

(2) Concentrating waste into a small area results in the population exposed to toxicants emitted from the waste receiving a higher dose;

(3) Since the degree of harm posed by exposure to toxic chemicals is a function of the level of exposure, concentrating wastes into a small area is potentially more dangerous to human health and the environment;

(4) Leaching or leakage of toxic chemicals present in a waste disposed of in a landfill can result in contamination of potable groundwater supplies;

(5) Landfilling is believed to be the most prevalent waste disposal method and therefore the method most appropriate for modelling;

(6) The Agency believes that due to the lower cost of disposal, industrial waste not brought under Subtitle C control will likely be disposed of along with municipal trash and refuse in landfills.

The Agency thus concluded that since landfill disposal appeared to be the most common method of disposal and appeared to present a great potential for groundwater degradation, it would be the management scenario to model in these initial regulations.

b. Choice of Degree of Simulated Leaching Activity

1) The Leaching Simulation Test

After determining that the toxicity characteristic should evaluate the potential hazards posed by improper waste landfilling and subsequent environmental release via a groundwater exposure pathway, the Agency next had to decide how to measure wastes' potential to release hazardous constituents to groundwater under these circumstances, i.e., wastes' capacity to leach hazardous constituents if improperly landfilled. The key question thus became what degree of leaching activity the test should induce.

In devising this test, the Agency was guided by the statutory definition of hazardous waste, which commands implicitly that any test to determine hazardousness be aggressive, since all wastes potentially capable of causing substantial hazard if improperly managed are to be regulated as hazardous. At the same time, there must be some upward limit on the aggressiveness of a test, since virtually any substance can be hazardous if sufficiently mismanaged (for instance, dumped directly into a drinking water supply), yet the statute does not contemplate Subtitle C regulation of all wastes. The Agency thus determined that a test which simulates a degree

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of leaching activity very unlikely to occur in most waste management practice is overly aggressive.

The leaching test, contained in the characteristic, known as the Extraction Procedure (EP), is designed to satisfy these competing considerations. As will be explained in greater detail below, the test assumes wastes will be exposed to an acidic leachate medium with pH of 5. This leachate medium tends to leach waste constituents (particularly metals) relatively aggressively, yet, as discussed below, is not so aggressive as to simulate a level of leaching activity beyond that which could realistically occur.

The choice of the leachate medium selected was premised on a specific physical model, which is described below. Importantly, however, the Agency believes that the predicted degree of contaminant concentrations in leachate could reasonably occur in the course of most waste management, whether or not the specific waste management conforms to this physical model.

The specific environment contemplated by the Agency in developing a leachate test is an improperly designed and managed municipal landfill. This type of landfill generally becomes acidic during its lifetime at which time the degree of leaching induced is relatively high.* The Agency's concern is that potentially hazardous wastes, if not brought within the Subtitle C system, may be sent to municipal landfills, with a resulting high level of leaching activity and environmental insult if the landfill was not designed specifically to prevent migration of leachate into the environment. This concern was shared by the Congress in promulgating Subtitle C:

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*Specific features of this model are,

-- the landfill receives predominantly domestic refuse or, if not domestic refuse, material with similar chemical, biological, and toxicological properties (i.e., only 5% of the fill is industrial in nature).

-- the character of the leaching fluid that the waste will be exposed to is predominantly a function of the nonindustrial material in the landfill.

> Even more threatening are the present disposal practices for hazardous waste ... In many instances these hazardous wastes are disposed of in the same manner and location as municipal refuse -- in the local landfill. H. Rep. No. 94-1491, supra, at 12.

These wastes' potential to cause harm in this environment therefore should be evaluated.*

2) Arguments That The Leaching Test is Overly Agressive

A great many comments were received attacking this portion of the characteristic as being overly aggressive because the commenters' wastes are not placed in municipal landfills. To the extent that these comments stated only that individual generators chose not to send their wastes to municipal landfills the comments are misplaced since the wastes may still potentially be managed in municipal landfills (absent Subtitle C regulation).

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*A specific discussion of how the leaching test simulates municipal landfill waste management conditions appears later in this document.

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Certain generators,* however, stressed that their wastes are not managed in municipal landfills, and are highly unlikely ever to be so managed whether or not the wastes are regulated under subtitle C. The Agency remains convinced that the degree of contamination indicated by the EP is nevertheless sufficiently predictive of what may occur even in purely industrial waste management practice to be a regulatorily valid means of evaluating hazardousness of these wastes. First, even wastes such as these may reasonably come in contact with mildly acidic leaching media (i.e., pH of approximately 5) during their management histories. For example, waste acid streams are often disposed along with large volume waste streams. (13) Acid rainfall and water passing through acidic soils may be other sources of acidic leaching solution. Other wastes, although normally considered to be neutral or basic, may contain acidic constituents which can be released on contact with water or air to create acidic leaching conditions. Many mining wastes, for example, contain pyritic sulfur, which upon exposure to air and rain forms sulfuric acid, resulting in acidic leachate. Other types of improper waste management may also result in exposure of waste to acidic leaching conditions.*

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*Among these generators are a number of large volume waste generators, such as electric utilities and mining wastes.

Furthermore, large volume wastes may cause an equivalent degree of contamination even if not subject to acidic leaching conditions. The large volume of waste present in the site tends to lead to increased toxicant concentrations. This effect comes about because the water (e.g., rain) acting on the waste travels through a larger amount of waste before entering the environment. The leachate thus tends to become saturated with the contaminants. By contrast, in municipal landfills, the small volume of industrial waste present limits the contact time in which toxicants can act to saturate the leachate.

The Agency therefore believes there is at least the potential for most wastes to come in contact with an acidic leachate medium, or to cause equivalent degrees of contamination, so that the wastes' potential to cause harm if improperly managed can reasonably be measured by assuming the presence of acidic conditions. It should be noted further, that the Agency is not legally obliged to model precisely the circumstances of individual waste management sites, or classes of waste management sites, in making determinations of hazardousness. Not only does the statutory definition of hazardous waste itself afford the Administrator great leeway, but courts in other contexts have upheld national environmental standards based upon physical models which did not conform precisely to physical circumstances of affected facilities. *See*, *e.g.*, *Sierra Club* v. *EPA*, 540 F.2d 1114, 1136 (D.C. Cir. 1976), vac. for further consideration in light of Clean Air Act Amendments of 1977, and to consider the suggestion of mootness, *sub nom*. *Montana Power Co*. v. *EPA*, 434 U.S. 809 (1977) (EPA's air pollutant diffusion model is upheld as a valid means of establishing emission standards for proposed new sources under prevention of significant deterioration regulations, even though the model is admittedly imprecise in predicting the effect new sources will have on ambient air, the court stating, "so long as the method of measurement is consistent, it may be used as a reliable benchmark of the relative impact of different sources"); *State of Texas* v. *EPA*, 499 F.2d 289, 301 (1974) *cert*. *denied*, 427 U.S. 905 (1975) (hydrocarbon emission reduction standard established on the basis of a "simplistic" physical model is upheld; use of the model is not an arbitrary or capricious exercise of authority); Hercules, Inc. v. EPA, 598 F.2d 91, 104-106 (D.C. Cir. 1978) (toxic effluent standard for toxaphene established on the basis of toxaphene's effect on an aquatic species not found in the receiving waters of the sole discharger).*

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*A number of commenters agreed that their wastes could come in contact with acidic leachate media even though not managed in municipal landfills, but argued that the acidic leachate would be buffered (i.e., neutralized) to a greater degree than would acidic leachate in a municipal landfill, which would in turn result in a lesser degree of waste constituent solubilization. The degree of buffering in particular waste management settings is, however, very difficult to quantify, and the Agency believes its leachate test strikes a reasonable balance. The test in the first instance uses a relatively mild acid and further takes buffering capacity into account by limiting the amount of acid used in performing the extraction. In the case of wastes with high buffering capacities, therefore, the waste itself largely determines the leaching media composition. The degree of buffering predicted, while obviously not precisely accurate for every waste management situation, is believed to be sufficiently representative for use in the protocol.

It should also be mentioned that the phenomenon of leaching over the life of a waste management facility is incompletely understood, and can be characterized legitimately as "on the frontiers of scientific knowledge . . ." Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974). There is also no consensus within the scientific community as to an appropriate short-term extraction test to measure this phenomenon. Health-based regulations addressing such areas of uncertainty have traditionally been accorded considerable judicial deference. Hodgson, supra, 499 F.2d at 474-76; Ethyl Corp. v. EPA, 541 F.2d 1, 24-29 and cases there cited (D.C. Cir. 1976, en banc). Again, under these circumstances, some imprecision in the leaching test is not only acceptable, but eminently justifiable. As the court stated in Ethyl Corp., supra:

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*It should be noted further that in each of these cases, the physical model was used to establish a quantitative discharge standard, as compared to the present situation where a model is used only to make a screening determination of wastes which must be regulated to ensure proper management, a less precise undertaking. This situation is consequently a fortiori from the cited cases.

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> Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a prescience that removes all doubt from their decision making. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or non-existent data base upon which to draw? Sometimes, of course, relatively certain proof of danger or harm from such modifications can be readily found. But, more commonly, reasonable medical concerns and theory long precede certainty. Yet the statutes--and common sense--demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable. Ethyl Corp., supra, 541 F.2d at 24-25.

3) Arguments That the Leaching Test is Insufficiently Aggressive

The Agency's proposed leaching test (and the EP Toxicity Characteristic as a whole) was also criticized as being insufficiently aggressive because the test was not "designed on the assumption that the waste will be disposed of in the worst possible environment."* As noted above, however, the Agency does not believe it is justified, nor is it advisable to base a determination of hazardousness upon waste mismanagement assumptions -- including assumptions as to leachate medium composition -- which are very unlikely to occur in practice.

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*Report on Hazardous Waste Disposal, Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 96th Cong. 1st Sess. 53; see also Comments of Environmental Defense Fund, March 16, 1979, pp. 9-10.

Moreover, it should be remembered that the Extraction Procedure Toxicity Characteristic (of which the leaching test is a part) is not the sole means of bringing solid wastes within the subtitle C regulatory framework. The other mechanism, listing of hazardous wastes, allows the Agency to interpret leachate data in a more individualized way, and to take into consideration additional factors, such as indications of actual waste mismanagement or unusual waste management practices, which are not measured by the characteristic.* Thus, the Agency has not ignored all waste mismanagement situations beyond the situation modeled in the toxicity characteristic; it has chosen to take them into account in a more individualized manner.

The Agency believes this course preferable to basing a test upon an assumption of absolute worst-case mismanagement. If a generator's waste fails the test, the waste is irrevocably within the subtitle C system. In the Agency's view, this requires some safeguard in the test against indiscriminate overinclusion, which overinclusion might result from a leaching test based upon assumptions of unusually deficient waste management.* The Agency therefore chose what it regards as a plausibly-occurring type of mismanagement model on which to base its leaching test and toxicity characteristic.

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*See, for example, Listing Background Documents for Chromium Pigments, Secondary Smelting and Refining of Lead, and Primary Smelting and Refining of Lead, all of which list wastes which conceivably might not fail the toxicity characteristic but still pose a substantial potential hazard because of the presence of additional factors not evaluated by the extraction procedure.

c. Remaining Features of the Waste Disposal Model

Once a constituent is leached from the waste matrix, there remains the question of its environmental fate: does the constituent have sufficient mobility to pass through soils and reach groundwater, and if it reaches groundwater, is it persistent enough to reach environmental receptors in concentrations sufficient to create a potential substantial hazard. In evaluating these considerations, it is assumed that disposal will occur in an environmentally sensitive area, and that waste constituents will undergo some attenuation in both soil and groundwater before reaching environmental receptors. The postulated features of the hypothetical model which reflect these assumptions are:

> -- The waste landfill is situated over an aquifer that serves as the sole source of drinking water for a significant number of people;
>
> -- The soil below the site is composed of material with limited attenuative capacity;
>
> -- Persons using the aquifer as a source of drinking water are being supplied from wells which are situated 150 meters (500 feet) downplume of the disposal site and draw water from the plume of contaminated water.

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*By contrast, a listing determination is not irrevocable since individual generators may petition the Administrator to have their waste delisted. See §261.39.

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As is discussed later in this background document, a rate of leachate constituent attenuation is then projected based upon this model.

As with the leachate simulation test, a plausibly occurring type of worst-case mismanagement is assumed. With respect to the assumption that disposal occurs in an environmentally sensitive area, no other assumption would be warranted in light of the statutory mandate to protect against groundwater degradation (as well as to protect human health and the environment). Obviously, any characteristic must be designed not only to protect against mismanagement occurring in areas of relatively low mismanagement potential but also in areas of high potential. Indeed, the assumption of mismanagement in environmentally sensitive areas was not seriously challenged by any commenter.

The decision to take attenuation into account also appears to be both straightforward and desirable. There is clearly sufficient physical evidence of environmental attenuation for the Agency to assume that waste constituents will undergo some degree of attenuation before reaching environmental receptors. This type of approach has in fact been adopted by EPA in other environmental programs, with judicial acceptance. See, e.g., Hercules, Inc. v. EPA, supra, 598 F. 2d at 115-17 (mixing zone factor used in establishing toxic effluent discharge standard).

3. Thresholds to Determine Unacceptable Levels of Contamination

The final major assumption contained in the toxicity characteristic is the choice of thresholds to determine unacceptable levels of contamination. Obviously, if a test is used to measure toxicity, contaminant concentrations in the test extract need to be related to a numerical standard, viz., what concentrations of what contaminants give rise to a substantial potential hazard. For these values to be defensible, they should be based on recognized human exposure health effect thresholds.

When the Agency evaluated the available toxicological information it was found that the only available established benchmarks for toxic contamination of drinking water which were both scientifically recognized and which address chronic exposure were the National Interim Primary Drinking Water Standards (NIPDWS).* These standards were developed pursuant to §1412 of the Public Health Service Act as amended by the Safe Drinking Water Act to protect the nation's supply of potable water. They reflect the best available scientific information relative to safe levels for 14 potentially toxic species in drinking water.

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*The current approach used in the California hazardous waste program, which has been recommended as a model for the Federal regulations (see, e.g., Report on Hazardous Waste Disposal, supra, at 40), is not based upon contaminant thresholds, and thus provided no guidance in developing such thresholds.

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The comment was made that the Agency should broaden the coverage of the Toxicity Characteristic by incorporating the "Water Quality Criteria" in addition to the Interim Primary Drinking Water Standards. As was described in the Proposed Regulation, this approach was initially considered but rejected. The principal reasons for not using the criteria are:

(1) The unavailability of the needed guidelines, and

(2) the lack of available resources in the regulated community to implement such an approach if adopted.

During the time regulations under section 3001 were being developed, Water Quality Criteria for the 65 pollutants listed as toxic under the Clean Water Act were first being formulated. The preliminary drafts then available received substantial negative comment from the scientific community, both from within and from outside the Agency. The Agency thus believed that it would be a long time before the final Water Quality Criteria were available, and further felt that it was inadvisable to delay proposal of RCRA regulations until the criteria were available.*

The second reason why use of the Water Quality Criteria was not believed to be viable relates to the insufficient scientific resources to implement such a regulatory approach. In order to implement a self-determinative regulatory program which requires generators to test all wastes for a list of toxic species, reliable, standardized testing protocols are required. Secondly, the regulated community has to have available to it sufficient testing capability (i.e., in-house or through contractors) to conduct the required tests. At the time the section 3001 regulations were proposed, and to a great extent still today, such reliable standardized methodology was not available. Furthermore, the personnel and laboratory facilities to perform the analyses that would be required under such a regulatory approach are not available.

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*As it turned out, the first group of criteria were eventually proposed on March 15, 1979, a full three months after the RCRA section 3001 regulations were proposed. The last of the 65 were proposed on October 1, 1979. Final promulgation of the first group is presently scheduled for this summer.

In summary, the Agency believed the suggested approach (i.e., expand the characteristic by including threshholds for the 65 toxics for which Water Quality Criteria are being developed) was impossible to carry out and thus the present listing approach was adopted. It should also be emphasized that the Agency may still bring into the hazardous waste control system any wastes that contain toxicologically significant quantities of any of the 65 toxicants for which Water Quality Criteria are being developed by listing specific waste streams. Many of the waste streams listed in today's Federal Register in fact are based upon the presence of many

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of these 65 toxicants, as well as upon the presence of other toxicants not included within either the list of Water Quality Criteria pollutants or the pollutants measured by the Extraction Procedure Toxicity Characteristic.

III. RATIONALE FOR THE EXTRACTION PROCEDURE

For purposes of easier comprehensibility of the following discussion, a description of the proposed Extraction Procedure (EP) is given at this point. The background document then goes on to decribe the genesis of the EP, the decision to use batch tests in the protocol, the issue of whether the test should be designed to measure maximum concentration or cumulative release of waste contaminants, and the physical justification for the various steps of the EP.

The proposed EP consisted of a series of steps. First a representative sample of the waste was obtained. The solid portion of the waste was then separated from the liquid portion by means of filtration and centrifugation. Next, the solid portion was ground, or subjected to a compaction force test for structural stability, and placed in an extractor where it was extracted with water acidified with acetic acid. This mixture was agitated and extracted for a period of 24 hours. At the end of the 24 hours the mixture was again filtered and the resulting liquid extract was combined with the liquid portion which was originally separated out. The combined extract was then analyzed for its constituent contaminants. If analysis revealed that the extract contained NIPDWS contaminants in concentrations greater than 10 times those specified in the National Interim Primary Drinking Water Standards, the waste was considered hazardous.

A. GENESIS OF THE EXTRATION PROCEDURE

When the Agency embarked on the devlopment of a testing procedure to detect wastes capable of leaching toxic constituents into groundwater, there were no standard methods for measuring the leaching potential of a waste. For that matter, the processes governing the formation of leachate in landfills were only partially understood. Accordingly, EPA initiated two parallel research efforts to develop a standardized testing procedure to measure leaching potential. The first was a grant awarded to researchers at the University of Wisconsin in July 1976. This study, referred to hereafter as the Ham study, was commissioned to study the process of leachate generation from landfilled wastes, to evaluate the factors which influence leachate generation and to develop a leaching test suitable for assessing the leaching chara-acteristics of such wastes. This study was completed in July 1978 and the results published in a May 1979 report entitled Background Study on the Development of a Standard Leaching Test (14).

The second research effort was a grant awarded to the Mitre Corporation to compile information on existing leaching tests and to evaluate the usefulness of these tests in assessing the leaching potential of a waste. Work on this grant was completed in February 1978, and the results published in a report entitled the Compilation and Evaluation of Leaching Test Methods (15). This report discussed the environmental factors which influence leachate generation and evaluated 26 different leaching tests for their utility in assessing the leaching characteristics of a waste. The Mitre report recommended that EPA single out for further evaluation the leaching test developed by IU Conversion Systems, the leaching test developed by the State

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of Minnesota, and the leaching test being developed by Ham, et. al. at the University of Wisconsin. A study of these three tests was conducted by Ham as an adjunct to his other study and the results published in a July 1979 report entitled Comparison of Three Waste Leaching Tests (16).

While these studies were going on, EPA -- as a consequence of the time constraints mandated by Congress for promulgating the regulations -- entered into an agreement with the Department of Energy's Oak Ridge National Laboratory (ORNL) to conduct research into the toxicity of the extracts or leachates generated by the test procedure then under development by Ham. It soon became apparent that the extraction fluid developed by Ham was too toxic to permit its use in bioassay tests to determine whether toxic materials were leaching from the wastes. EPA was concerned because it wanted to be able to assess the toxicity of the waste leachate through bioassay procedures as well as through analytical detection of the leachate constituents.* [See the Draft Toxicity Background Document prepared in support of the proposed regulations.(6)] An additional concern with the Ham test was that it might be too site-specific.

Consequently, in the fall of 1977, EPA modified the agreement with ORNL to allow work to be performed in developing a leaching procedure suitable for use with bioassays (although still relatively agressive). Relying heavily on the work already done by Ham and Mitre and on the work done by other groups, such as the American Society for Testing and Materials (ASTM), ORNL assisted the Agency in developing the Extraction Procedure set forth in the proposed regulations.

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*Although the finally promulgated test does not provide for bioassay tests on the waste extract, EPA envisions possible incorporation of such tests into the EP in the future.

B. CHOICE OF A BATCH TEST

While a number of aspects of aspects about the EP, as finally proposed, were not settled until relatively late in the development process, some were settled early. As noted in the Ham study there are two general approaches to evaluating the leaching potential of a waste: (1) a very intensive study of the leaching characteristic of both the waste and its desposal or (2) a quick test using standardized procedures (14). Clearly, the intensive study -- which is very expensive and takes a great deal of time -- is unsuitable for use in the laboratory regime contemplated by the Act. Consequently, EPA decided early on to utilize a short-term standardized test as the device for assessing the leaching potential of a waste.

There are two types of short-term tests commonly used to assess the leaching potential of a waste: (1) batch or shake tests and (2) column tests. Batch tests are performed by placing a representative sample of the waste to be tested in a container along with the leaching solution. The mixture is then generally agitated for a specific period of time and the resulting elutriate or leachate separated from the remaining solid and analyzed for its constituents. Such tests are cheaper, faster and more reproducible than column tests, but the test procedures must be carefully modeled upon actual landfill conditions if the information obtained is to be at all meaningful. Column tests are performed by placing the waste in a column and passing the leaching solution through. Such tests can give a better simulation of landfill conditions than batch tests. However, these tests suffer from a number of disadvantages, including:

--channeling and nonuniform packing

--unnatural clogging

--unnatural biological effects

--edge effects

--lengthy time requirements for running the test (months to years)

--lack of reproducibility (17).

In light of the above difficulties, particularly the lengthy time requirements for running column tests, EPA chose to employ a standardized batch test as the means for assessing waste leaching potential.

C. MAXIMUM CONCENTRATION VERSUS CUMULATIVE RELEASE

Ham considered it important for a leaching test to provide an indication of both the maximum concentration of toxic constituents likely to be attained in the leachate and the cumulative release of toxic constituents from the waste over time (14). EPA on the other hand, considers the maximum concentration of toxic constituents in the leachate to be the factor which primarily identifies the environmental hazard presented by the waste. This is because the concentration of

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toxic constituents in the groundwater rather than the aggregate quantities released thereto determines the health hazard posed by groundwater contamination, although of course the two are related.

EPA also considers maximum concentration to be more important than cumulative release because of the lengthy residence time of contaminants in the groundwater. Unlike surface waters, groundwater is not continually flushing itself out; consequently, the aggregate contribution of pollutants is not as important as in surface water pollution. Accordingly, EPA has structured the EP so as to concentrate on the maximum concentration of contaminants in the leachate.

D. EXPLANATION OF HOW THE EP MODELS PHYSICAL FACTORS WHICH INFLUENCE LEACHATE FORMATION IN THE ASSUMED DISPOSAL ENVIRONMENT

The Extraction Procedure is designed to evaluate a waste's capacity to release hazardous constituents to the environment if the wastes are improperly landfilled in a plausibly occurring manner, and to gauge the resulting risk of substantial potential hazard. It thus becomes important to identify and replicate reasonably the principal physical processes and environmental factors influencing leachate formation and subsequent environmental contamination. These processes and factors include:

(1) Leaching medium composition;

(2) The amount of leachate medium to which the waste is exposed;

(3) Surface area, particle size, and composition of the material being leached;

(4) Contact time between the leachate medium and the waste and;

(5) Attenuative capacity of the soil and of the underlying aquifer.

The operative aspects of the extraction procedure (both the proposed and the final EP) -- i.e., the aspects of the procedure which model these factors -- are:

(1) Solid material particle size reduction;

(2) Phase separation;

(3) Leaching medium composition;

(4) Ratio of waste to extractant (solid-liquid ratio);

(5) Aggressiveness of agitation;

(6) Waste-extractant contact time;

(7) Assumed level of environmental attenuation.

A full discussion of the EP's component parts and how these parts relate to the physical processes which the EP attempts to model is set forth in the following pages.

1. Sample Preparation

a. Liquid-Solid Separation

Ham surmises that after a waste is deposited in a landfill the solid and liquid components of the waste will separate independent of any leaching action. (14) The liquid component of the waste might flow downward due to gravity, be absorbed by surrounding materials, or flow away from the waste by capillary action. After separation, only the solid material left behind will be subjected to leaching action by available leaching media.

EPA therefore believes that it is most appropriate to subject only the solid component of the waste to simulated leaching. Consequently, EPA has provided that the initial step in the EP is to separate the solid and liquid components of the waste. After extraction, the extract of the solid is combined with the original liquid phase of the waste to gauge the full extent of potential contamination posed by the waste.* This step models the situation

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*EPA recognizes that the separation of liquid and solid components in the waste will depend on site-specific conditions, and so might not occur invariably. Nevertheless, it believes that utilization of the solid-liquid separation technique recommended by Ham is justified. The Agency, as stated, is attempting to model worst case conditions, and separating the phases prior to extraction of the solid phase is the more aggressive test. Secondly, under this approach liquid wastes would tend to be rated as more hazardous than solid wastes containing the same concentration of a given toxicant. This result is believed reasonable since liquids are more mobile than solids and would tend to migrate more rapidly, and in a more concentrated manner than solids.

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where the liquid portion of the waste separates from the solid portion, flows downward and becomes absorbed onto other material in the fill. Later, leachate generated from the remaining solid migrates downward, displacing and mixing with the absorbed liquid phase and carrying it into the aquifer.

1) Sample Filtration

The Agency considered several techniques in performing the solid-liquid separation step, including filtration, sedimentation, centrifugation and screening. EPA considered filtration and centrifugation to be the most appropriate techniques and elected to make filtration the final step in the separation process, with centrifugation as a supplemental aid in separating wastes which cannot easily be separated by filtration alone.

The choice of a filter pore size has an important bearing on the ultimate concentration of toxic contaminants subjected to analysis, because the filter operationally defines both the liquid which is presumed to separate out from the waste and the leachate which is produced by the leaching process. In conformity with Ham's suggestion, EPA has selected a filter pore size of 0.45 microns because particles larger than 0.45 um are usually removed by passage through the soils, as indicated by the low suspended solids content of most groundwaters (14). It is therefore not unreasonable to assume that particles larger than .45 um will be filtered out by the soil and will not reach groundwater.

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The separation procedure can be described as follows. If the sample is not obviously a solid, an attempt should be made to filter it through a 0.45 um filter under a pressure differential of $\leq$ 75 psi. If clogging occurs, centrifugation is employed as an aid to the separation. Pressure filtration acts to accelerate the filtration process without changing the nature of the separation. Centrifugation is particularly useful where the nature of the mixture is such that even pressure filtration would require a large expenditure of time. Although at the time of the proposal the Agency believed that centrifugation could be used as a direct replacement for filtration, later information indicates that using centrifugation alone results in a carryover of particles greater than 0.45 um. Consequently, the final regulation provides that centrifugation is only to be used as an aid to the filtration process. After centrifugation a final filtration must be performed to remove particles greater than 0.45 um from the liquid phase and remove residual liquid from the solid phase. Anything that cannot be readily separated by filtration and centrifugation is considered a solid and is subjected to the leaching aspect of the test.*

A number of commenters said they encountered severe operational problems running the extract procedure on liquid wastes which contain a very low percentage of solids (e.g., <1% solids). To accomodate this problem, EPA has elected to amend the proposed regulation to provide that a sample which contains less than 0.5% solids need not undergo the leaching procedure. Rather, such a sample, after filtration, should be considered the extract and should be analyzed directly for its toxic constituents. (Filtration is necessary because of the assumption that only particles less than 0.45 um in size will appear in the leachate.) This change will make the EP considerably easier to perform for liquid wastes with very low solids content, while not appreciably altering total concentrations of toxic constituents in the extract, since extractions performed on the small amounts of solid present in such solutions are not likely to generate much in the way of toxic contaminants.*

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*Such wastes might include the thixotropic materials such as drilling muds and paints which were found to cause difficulty during evaluation of the separation procedure. (17,18). Since it is reasonable to assume that such wastes will not separate out in actual landfill conditions, such wastes should be treated as solids and extracted without separation.

b. Sample Homogenization/Particle Size Reduction (Including the Structural Integrity Procedure)

To insure reproducibility of the leaching test performed on the solid portion of the waste, a homogenous portion is required.

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*During evaluation of the separation procedure by Ham, ORNL, and EMSL-LV, very few operational problems were encountered, although one potentially serious problem has been noted by ORNL (6). Preliminary work indicates that the filtering of aqueous solutions containing polyaromatic hydrocarbons (PAH), using either Millipore, type HAWP, or Nuclepore, polycarbonate membrane filters, results in the solutions losing a substantial amount of their PAH content. If this effect is found to be the case generally for organics, it suggests that the non-polar toxicants may not show up in the extract in as large a concentration as they might in the real world. Unfortunately, the magnitude of the problem is not yet known and further work must be done before attempting to remedy the problem. If a solution turns out to be needed it will be incorporated into these regulations in the future.

This can best be accomplished by reducing the particle size of the waste through subdivision (e.g., grinding, cutting) -- a process which tends to equalize the surface area, geometry, and other such properties of the waste making up the sample. As a general matter, the more finely ground the waste, the more reproducible the test results are likely to be. At the same time, because grinding increases the surface are which comes into contact with the leaching medium, the finer the waste is ground, the higher the concentrations of contaminants in the extract.

It is difficult to gauge the extent to which reduction of waste particle size duplicates actual landfill conditions. The arguments that can be made on behalf of very fine grinding include the fact that wastes will eventually degrade in a landfill, and that fine grinding probably comes closest to representing the saturated conditions which occur when the leaching medium percolates slowly through a column of waste. However, very fine grinding tends to yield results which are probably not representative of wastes which have been treated for the purpose of reducing the mobility of the toxic species. A variety of these treatment processes have been developed -- including the incorporation of the waste into a solid matrix, the encapsulation of the waste in an impervious coating, and the addition of binders. These management techniques are designed expressly to prevent breakdown during disposal and need special consideration with regard to sample preparation.

To accomodate wastes which have been treated in an attempt to reduce the mobility of the toxic species or naturally are in a bound form, EPA has promulgated alternative sets of requirements. Wastes which have not been subjected to cementing processes or are otherwise not found in a monolithic or block form are required to be ground or otherwise subdivided such that they pass through a 9.5 mm (3/8 in) standard sieve. This requirement represents a compromise between the very fine grinding specified by the tests being developed by the states of Illinois (20) and California (21) and the use of a monolithic mass specified by ASTM (22) and IUCS (15).* Wastes which have been subjected to special encapsulation or fixing processes -- and are thus monolithic in form -- may instead be demonstrated to be structually stable and exempt from testing in a subdivided form through use of a special procedure called the Structural Integrity Procedure (SIP). The SIP is designed to be a moderately severe approximation of the disintegration that might be expected if heavy equipment passes over the waste.

Mahlock et al (23) have determined that a compaction test identical to the procedure of ASTM D-698-70, but using only 15 hammer blows, simulates the compactive effort that might be expected from passing earthmoving equipment over a placed landfill. Their

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*A few commenters complained that the requirement of passage through a 9.5 mm sieve is insufficiently flexible because it fails to accomodate certain waste particles which fail to pass through the sieve yet exhibit a surface area equivalent to waste particles which do pass through the sieve. EPA has taken care of this problem by specifying that the waste either be passed through a 9.5 mm (3/8") sieve or have a surface area equal to or greater than 3.1 cm^2/gm.

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15-blow test uses a (5.5-lb) hammer impacting on a (.0333 ft^3) cylinder of sample after dropping (12 in). This apparatus would exert an impact of (165 ft-lb/ft^3) on the sample:

$$v2 = 2 \text{ (acceleration of gravity) (distance)}$$

$$= 2\ (32.2 \text{ ft/sec}^2)\ \ (1 \text{ ft})$$

$$= 64.4 \text{ ft}^2/\text{sec}^2$$

$$\frac{\text{Kinetic energy}}{\text{volume of sample}} = \frac{1/2\ m\ v^2}{(1/30)}$$

$$= \frac{(.5)\ \ (5.5/32)\ \ (64.4)}{.0333}$$

$$= 165 \text{ ft-lb/ft}^3$$

EPA has decided to employ a modification of this procedure. The procedure selected is one based on a scaled down verion of Mahlock's 15-blow compaction procedure. The scaled down procedure uses a .32 Kg (0.73 lb) hammer acting on a (0.0022 ft^3) sample with a (6-in) free fall. This device (Figure 1) has approximately the same compaction action as the larger unit, as demonstrated by the equation below.

$$v^2 = 2\ a\ x$$

$$= (2)\ (32.2)\ (0.5)$$

$$= 32.2$$

$$\frac{\text{Kinetic energy}}{\text{volume of sample}} = \frac{1/2\ m\ v^2}{(.0022)}$$

$$= \frac{(0.5)\ \ (0.73/32)\ \ (32.2)}{(.0022)}$$

$$= 165 \text{ ft lb/ft}^3$$

The sample size designated by this procedure will be approximately 100 gms, which corresponds nicely with the minimum sample size required for extraction. To account for the cushioning or energy dissipation resulting from the compressibility of surrounding wastes, a resilient sample holder has been incorporated in the design.

Weeter and Phillips (24) evaluated this procedure using a flue gas dusulfurization sludge fixated by the addition of varying amounts of water. Three samples were used in an attempt to represent a full range of unconfined compressive strengths.

Table 1

Sludge Sample No.	Density (lb/ft^3)	21 day UCS[a] (lb/in^2)
A	50	81
B	120	586
C	101	1450[a]

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[a] Unconfined Compressive Strength

When subjected to a series of blows by the .32 Kg (0.73 lb) hammer, sample A cracked throughout the upper half of the cylinder, and the bottom half remained intact. The pulverized particles formed in the upper half of the cylinder seemed to dissipate much of the energy exerted by the hammer after the third or fourth blow. As a result, the succeeding blows had little effect on the remaining structure of the cylinder. No visible change in structure was noted in specimens B and C after the SIP procedure.

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One shortcoming of the SIP as currently formulated is the lack of any measure of weatherability. Wastes deposited in or on the land will be subjected to the effects of water, freeze-thaw cycles, and seasonal and daily temperature changes. EPA intends to explore these factors to determine if a testing procedure can be devised which incorporates these additional factors.

2. Leaching Media Composition

It has been demonstrated empirically that the leaching media to which a waste is exposed, whether it be water, an acidic solution or whatever, has an important influence on the ultimate concentrations of toxic contaminants in the leachate. Consequently, the choice of a leaching medium (extractant) has an important bearing on the aggressiveness and ultimate shape of any leaching test.

As was explained previously in this document, EPA chose to model the leaching medium employed in the EP upon the leaching medium likely to be found in an actively decomposing municipal landfill. This was based on several considerations. First, given the considerable uncertainty and lack of information concerning the phenomenon of long term leaching, as well as its statutory mandate, the Agency believed it should be reasonably conservative in its choice of a leaching environment to model. Second, the Agency was convinced that most categories of waste have the potential of being disposed in municipal landfills. Third, the Agency believed that even wastes which are unlikely to be disposed of in municipal landfills are reasonably likely to come into contact

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with a mildly acidic leaching medium at some point in their management histories. Finally, the level of leaching activity predicted could also occur even if acidic leachate was not present.

The following discussion explains how the composition of the extraction medium simulates leaching media which could be present in municipal landfill.

There is ample evidence that pH of the extracting solution is the most important factor in modeling an expected level of leaching activity relative to metal migration (14).* Further, the pH of the leaching media of a decomposing municipal landfill leachate will generally be acidic sometime during its lifetime, due to the presence of biodegrading refuse (14). The Agency therefore chose an acidic leachate composition, consisting of an acetic acid solution with a pH of 5.

Acetic acid was chosen because it is the most prevalent acid found in municipal landfill leachate (14). The pH value selected is well within the reported ranges of pH levels for municipal landfills, as shown in the following table:

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*Other important factors include solution buffering capacity, complexing capacity, redox potential, organic solvency and ionic strength (14).

Table 2. pH RANGES REPORTED BY VARIOUS AUTHORS FROM LANDFILL OR LITERATURE SURVEYS (14)

Source	pH Range
Chian et al.	3.7 - 8.5
Steiner et al.	4.0 - 8.5
Clark et al.	1.5 a/ - 9.5
Encom Associates	3.0 - 8.5
Pohland	4.9 - 8.4

a/ Site received acidic industrial wastes.

Furthermore, the pH value selected promotes relatively aggressive leaching of elemental waste constituents, and so furthers the Agency's statutory mandate of protection of human health and the environment.

Another important physical feature influencing toxicant concentrations in leachate is buffering capacity. The ultimate buffering capacity of real world leachates is a consideration which has received little attention from the research community. Data gathered at EPA's Boone County Field Site (25) over a period of 7 years indicates that the leachate generated by decomposing municipal waste contains approximately 0.14 equivalents of acidity per kilogram of dry refuse. Applying this data to the hypothetical disposal environment (containing 5% industrial waste and 95% organic refuse), EPA concluded that 1 gram of industrial waste could potentially be acted upon by approximatley 2 milliequivalents of acid. Translating this into the terms of the test, EPA determined that it should set a limit on total acid added to the extraction solution of 2.0 milliequivalents of acid per gram of solid material or 4 ml of 0.5 N acetic acid per gram of waste being extracted.

Certain other chemical parameters, notably extractant complexing capacity and redox potential, are not incorporated in the EP leaching medium (or are incorporated only to a limited degree). However, the Agency's failure to exactly replicate municipal landfill leachate is not necessarily a shortcoming. The ultimate regulatory objective is not to precisely model leachate from a municipal landfill, but to devise a protocol which is reasonably predictive of ultimate levels of leaching activity of a great variety of wastes. EPA believes that the present protocol largely achieves this objective relative to mobilization of metals and, to a limited extent, organics, and is thus promulgating the EP in the present form. EPA is studying this issue further, however, and if it appears that the protocol requires modifications in order to remain reasonably representative, appropriate revisions will be made.

The Agency is aware of one potentially serious regulatory deficiency in its choice of leachate medium composition. Studies performed by ORNL demonstrate that EPA's leaching solution (and Ham's synthetic solution) are deficient in their ability to adequately model the organic solubilizing ability of real world leaching media (7).* Since the characteristic is at present designed principally to evaluate leaching propensity of elemental,rather than organic contaminants, this deficiency is not deemed severe enough to warrant additional delay inplementing the characteristic. EPA is, however, working to develop a leaching media which reflects more accurately wastes' capacity to leach organic toxicants.

3. Sample to Extractant Ratio

The solid-liquid ratio, that is, the ratio of the quantity of solid waste to the quantity of leaching solution used, can be an important factor in assessing the leachability of a waste, since the greater the amount of waste present in the liquid, the more toxic species there are to be dissolved and the higher their concentration.**

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*This is probably attributable to the failure of EPA's leaching solution and possibly Ham's as well to include species such as fatty acids, alcohols and humic acids which have a great deal of organic character (7).

**This dependency of concentration on solid-liquid ratio is particularly characteristic of species whose concentration is not controlled by a solubility equilibrium. On the other hand, where the concentration of the toxic species is controlled exclusively by solubility equilibrium, the concentration of the species will not vary with the solid-liquid ratio, although Ham's experience suggests that there are very few such species (14).

A high solid-liquid ratio is probably better representative of actual landfill conditions, inasmuch as the solid-liquid ratio encountered by a drop of leachate percolating through a landfill is likely to be very high. In addition, a high solid-liquid ratio is more likely to reflect the maximum attainable concentrations which are the principal focus of EPA's concern. At the same time, a high solid-liquid ratio can cause difficulties with stirring or separation and can cause the system to become saturated with readily soluble salts -- with the result that the less soluble but more toxic species are left behind in the waste. A low solid-liquid ratio will promote greater ease of operation but will tend to magnify sampling and analytical errors.

After considering the above factors, EPA has elected to use a 1:20 solid-liquid ratio. EPA believes this ratio will attain reasonably high concentrations while preserving operational precision. Furthermore the ratio selected is well within the bounds of the ratios used in other comparable leaching tests, as shown in the following table, and is therefore believed to be an acceptable value.

Table 3. SOLID - LIQUID RATIO LEVELS UTILIZED IN OTHER LEACHATE TESTS (15)

Test	Solid - Liquid Ratio
IUCS	1:4
University of Wisconsin Standard Leaching Test	1:10
State of Delaware	1:25
State of Minnesota	1:40

4. Agitation Methods, Number of Elutions, and Extraction Contact Time

Apart from the solid-liquid ratio, already discussed, the remaining parts of the EP which have the greatest bearing on the concentration of toxic constituents in the leachate are the agitation method, the number of elutions performed, and the contact time between leaching solution and the waste. These are discussed below.

a. Agitation Method

To ensure that the surface area of the waste is sufficiently exposed to the synthetic leaching solution to replicate the effects of a leaching medium percolating slowly through a landfill, and to ensure reproducibile results, it is important to employ a uniform, non-destructive, efficient agitation. Ham evaluated the following five agitation methods:

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1. Continuous shaking (Gyrotory/Shaker, New Brunswick Scientific Co.)
2. Continuous mechanical paddle stirrring (Phipps and Bird, Inc. Richmond Va.)
3. Intermittent shaking by hand
4. Swing-type shaking
5. Rotating at two different angles

Ham concluded that none of these methods resulted in appreciably greater release of toxic constituents, although the rotating method gave the highest release. On the basis of the higher release figures for the rotating method and visual observtions which suggested that rotating at two different angles gave the best solid-liquid contact, Ham recommended use of the rotating method (14).

The Agency has, on its own, developed a stirring method which is useable with a wide variety of wastes and will permit the pH of the solution to be continuously monitored and adjusted using automated equipment. This device is illustrated in Figure 1 (see p.6). ORNL found that this device gave adequate agitation when rotational speeds greater than 40 rpm were employed. (7,19)

Rather than require use of this or any other particular equipment, EPA has decided, to simply specify that a suitable agitator or extractor is one which "will not only prevent stratification of sample and extraction fluid but also insure that all sample surfaces are continuously brought into contact

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with well mixed extraction fluid." This is being done with the intention of providing the regulated community with the greatest flexibility in obtaining a suitable extractor. A number of commenters interpreted the proposed regulations to require that agitation be performed with a particular piece of equipment manufactured by the Associated Design and Manufacturing Co. (i.e., the equipment EPA employed in many of its own laboratory studies). This is not the case. The proposed regulation and the final regulation allow the use of any piece of equipment that meets the general objective of insuring sufficient agitation so that stratification of the sample and extractant fluid does not limit the extraction of potential contaminants. This will give the regulated community the greatest flexibility in the choice of extraction equipment.

Extractors other than the one developed by EPA have been developed for use in evaluating wastes. One additional device that deserves mention (26) (Figure 3) uses a simple jig to hold and rotate a number of jars containing samples of waste and extractant fluid. Other extractors or agitation devices are under study. The results of these evaluations will be made public as they become available.

b. Extraction Contact Time

Ideally waste should be kept in contact with the leaching solution long enough to insure that maximum concentrations of the toxic contaminants are obtained. Unfortunately, however, this is not always possible because small amounts

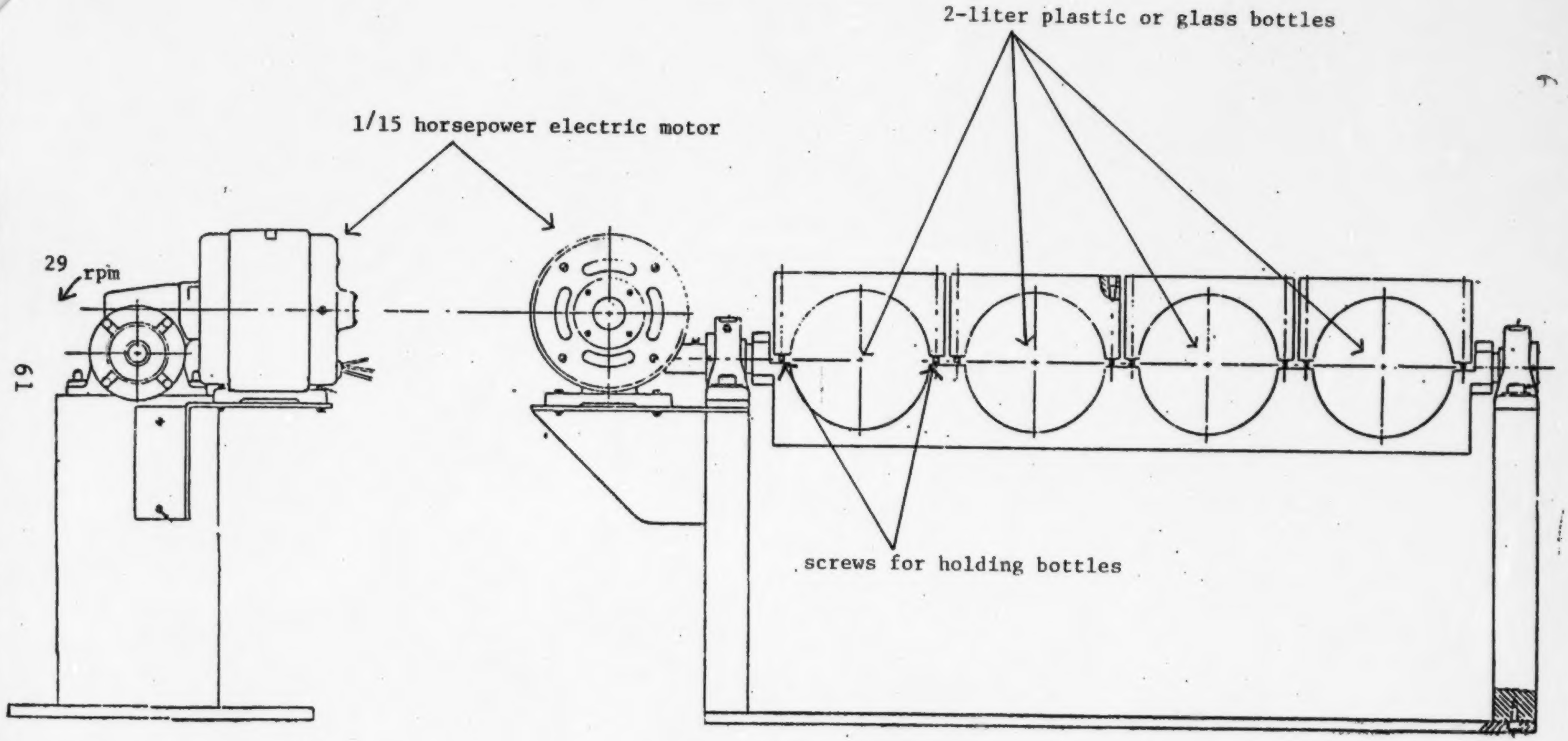
2-liter plastic or glass bottles
1/15 horsepower electric motor
29 rpm
screws for holding bottles

Figure 3
Rotary Extractor

of material may continue to leach from the waste for years.

Ham conducted research into the effects of elution time on cumulative contaminant release. He ran four elutions of varying duration on the waste--i.e., durations of 2 hours, 24 hours, 48 hours and 72 hours. After each elution, the liquid was filtered and analyzed for its constituents and the waste was contacted with an elution of fresh leaching solution. The results showed that cumulative release after three elutions is lower with a two hour contact time. For contact times over 24 hours the results were variable and in no instance were equilibrium conditions apparently reached. Ham suggested that a leaching contact time of between 24-72 hours be chosen, largely for practical considerations (14).

The Mitre survey indicates that there is no consensus among the available leaching tests as to the appropriate contact time required to simulate landfill conditions (15). This survey indicates that the contact times used in the various tests can be broken down as follows:

Less than 24 hours - 39 percent
24 hours - 39 percent
Longer than 24 hours - 21 percent

In view of the above, EPA has chosen to employ a leaching contact time of 24 hours for the EP, based largely on practical considerations. The Ham research--although it dealt with the influence of contact time on cumulative release rather than maximum concentration--would appear to be applicable to maximum concentration-oriented procedures in its conclusion that the effect of employing an elution time longer than 24 hours is inconsistent. Consequently, the Agency has chosen a 24 hour contact time to for the convenience of the laboratory personnel.

A number of comments were received in relation to the EP contact time. Some thought the time to be too long and others thought it to be too short. The Agency acknowledges that, in some instances, at extraction time of longer than 24 hours might yield more information. It also recognizes that in some instances a longer extraction contact time might result in a somewhat more conservative test. It believes, however, that concentrations obtained during the 24 hour contact time for one elution sufficiently approximates the maximum obtainable concentrations to justify selection of this figure.

c. Number of Elutions

Ham's procedure for measuring maximum concentrations of toxic contaminants in the leachate consists of running successive extractions or contacts of the same leaching solution on fresh waste. His study of this procedure showed that in some cases, steady state maximum concentrations were obtained after a very few extractions while in other cases steady state concentrations were not obtained even after 28 extractions performed over the course of eleven weeks. The most rapid increase in concentration occurred in the first extraction. Ham concluded that there is no ideal number of extractions capable of generating maximum concentrations of all toxic species in the waste. Consequently, he recommended three contacts--primarily on the basis of practical considerations. (14)

EPA has determined that only one extraction need be performed for the EP. It recognizes that a greater number of contacts might result in higher concentrations. In the absence of any demonstration that one number is clearly better than another, however, and in view of the fact that the first contact gives the highest concentrations for any one elution, the Agency has elected to go the less conservative route and require only one extraction.

5. Post-Extraction Sample Handling

As noted above, EPA has made the assumption that the toxic species present in the liquid phase of the waste will migrate from the solid and eventually reach the underlying aquifer independent of any leaching action which takes place on the solid. In order to model this situation, the extract obtained from the solid phase of the waste is combined with the waste's original liquid phase prior to testing. While it usually is more convenient to analyze the combined liquids as one solution, in certain cases where a multiphasic mixture is obtained analysis may be more conveniently performed on the separate phases. In such situations the analytical results are mathematically combined, relative to the ratio of the phases, to determine the integrated Extraction Procedure extract concentrations.

Once wastes are extracted, the extract should be preserved in order to prevent changes in the extract which might result in spurious analytical or bioassay results. When extracts are to be subjected to conventional chemical analysis only, the applicable preservation methods described in the EPA publication "Test Methods for Evaluating Solid Wastes" (27) are employed. In the event bioassay test are performed on the extracts, they should only be preserved by refrigeration at 4°C. This will prevent the introduction of potentially toxic preservatives. Irrespective of what sample preservation technique is employed, extracts should be analyzed as soon as possible after generation to prevent possible problems. One such problem relates to the formation of precipitates. In some cases the Agency has found that precipitates form when the extract sits for a period of time. While problems relating to precipitate formation are readily overcome when the extract is to be analyzed (i.e., through employment of the digestion procedures described in the test methods specified for use in evaluating solid wastes) (27), precipitate formation can present a problem when bioassay procedures are used. The Agency will be conducting further studies to determine the magnitude of these potential problems.

IV. BASIS FOR ATTENUATION FACTOR USED IN RELATING NATIONAL INTERIM PRIMARY DRINKING WATER STANDARD TO EP EXTRACT VALUES

The Extraction Procedure is designed to predict the potential concentrations of toxic constituents which will leach from the waste matrix itself. There remains the question of what will happen to the leachate after it leaves the waste matrix and before it reaches the point of environmental exposure. To accomodate the attenuation in concentration that can be expected to occur as the waste passes through the soil barrier beneath the landfill into the groundwater aquifer and ultimately to a drinking source, the Agency formulated a dilution factor designed to acccount for expected attenuation in groundwater. This attenuation or dilution factor was calculated against the backdrop of the following fairly conservative assumptions:

(1) The waste landfill is situated over an aquifer that is a source of drinking water;

(2) The soil below the site is composed of material with limited attenuative capacity; and

(3) Persons using the aquifer as a source of drinking water are supplied from wells situated 150 meters (500 feet) downgradient from the landfill.

The choice of an attenuation factor reflecting real-world conditions has proven to be one of the most difficult tasks faced by the Agency in formulating the EP Toxicity

Characteristic. Although the various attenuation mechanisms themselves are understood reasonably well, the actual rate of attenuation is highly site-specific. Moreover, there is very little empirical data on attenuation occurring during actual waste management, compounding the difficulty of generalization. Under these circumstances, it is the Agency's view that the choice of an attenuation factor is at the present time as much a question of regulatory policy -- i.e. what should the scope of coverage of the toxicity characteristic be -- as of regulatory judgment relative to the expected degree of attenuation that might occur during any specific type of waste management. The Agency believes its initial choice of a dilution factor of 10, and its final choice of an attenuation factor of 100 are both justifiable by reference to physical processes--that is, available data supports either choice. The discussion below sets forth the physical data bearing on attenuative mechanisms affecting constituent concentrations in leachate. The policy considerations which determined the Agency's decision to increase the proposed dilution factor are then described.

A. ATTENUATION OF CONSTITUENT CONCENTRATIONS IN LEACHATE

Changes in the composition of leachate from a landfill are usually achieved through a series of reactions. As the leachate migrates, constituent concentration may be affected by passage through various media. During percolation through

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the landfill interior, some components will be removed by adsorptive and complexing reactions, and others will be added by waste solubilization. At the interface between the landfill and the underlying strata, some further components may be removed by precipitation, filtration of particles, and absorption on gel precipitates. The existence below the landfill of an unsaturated zone with a liquid and a gas phase increases the possibility of attenuation or delay of contaminants. In this zone, permeability is lower than that of an all-liquid environment, and flow rates will probably not be uniform, thereby allowing some solute dispersion. Some insignificant attenuation by chemical or biochemical processes may also occur depending on the thickness of the unsaturated zone. (28)

At the boundary between the unsaturated and saturated zones, leachate movement changes from vertical to predominantly horizontal flow. This is in keeping with the fact that water entering the ground first moves vertically through the unsaturated zone then enters the saturated zone and travels in a hydraulic gradient. (28) Groundwater flow is normally laminar (i.e., characterized by parallel adjacent flow paths), although mixing can occur during movement through large fissures or in the immediate vicinity of a pumping well which alters the flow pattern of the groundwater. (29)

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Leachate does not mix readily with groundwater but tends to move as a slug, a plume, or a mass of degraded water in a manner governed by the groundwater flow pattern, although differences in density and miscibility can cause variation in behavior between the plume of contaminated water and native water. The velocity of this slug or plume of contaminated water may be less than, equal to, or greater than that of groundwater. (30)

Pollutants entrained in groundwater flow tend to become attenuated with time and distance. The attenuation mechanisms involved include dilution, adsorption, dispersion, diffusion, precipitation, and degradation. The most significant of these mechanisms in the saturated zone may be dilution of the leachate as it follows flow paths through the aquifer. The rate of attenuation will be dependent on the local hydrogeologic framework. Leachate will tend to be contained at sites underlaid by fine grained, compact materials with low hydraulic conductivities (slate, shale, soft clays). Migration with attenuation is favored in formations exhibiting intergranular flow (sands, sandstones, sandy clays, gravels) and formations displaying marked fissure flow with an element of intergranular storage (chalk) if the intergranular conductivity is greater than the maximum recharge rate. Rapid leachate

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migration through coarse, unconsolidated gravel formations and fissured rocks such as limestone and granite allows little attenuation of pollutants. (30)

Where groundwater flow is rapid, leachate from a point source will form a long thin plume. Where groundwater flow is low, leachate may tend to disperse laterally. Distortion of the shape of the plume can also be caused by variations in permeability, the operation of a pumping well, and changes in the groundwater flow, recharge, and waste disposal rates, (which can cause the plume to expand or contract.) The plume of a leachate containing constituents having a greater susceptibility to attenuation will be smaller than that of one containing persistent contaminants. Additionally, a plume supported by constant input of leachate will ordinarily stabilize.

As can be seen from the above, the degree of pollutant attenuation within an aquifer basically depends on site-specific conditions; therefore it is impossible to choose a dilution factor that will be appropriate in all cases. While some sites may exhibit attenuations of 1,000-fold, others may show no attenuation at all. In some cases, with time, a site that originally exhibited a 1,000-fold attenuation may become saturated and begin to flush at the identical rate at which it is being charged.*

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*A recent EPA - sponsored synposium on assessing attenuation likewise reached the conclusion that leachate attenuation is difficult to quantify outside of site-specific conditions. See "Pollution Prediction Techniques for Waste Disposal Siting, a State-of-the-Art Assessment" (31)

The Agency has utilized mathematical models in formulating an attenuation factor for regulatory use (32). A mathematical model is a simplified representation of a real system, and while difficulties are often encountered in quantifying parameters and testing and verifying results under specific field conditions, the model can supply information on potential groundwater effects. A model to estimate leachate dilution in groundwater and downgradient well discharge has been devised at the Water Research Center of Medmenham Laboratory in England (33). This model also suggests that there may be a wide range of dilution factors even if only a relatively few variables are considered. The model is based on the following assumptions:

1. Leachate of consistent composition is discharged from the entire landfill at a constant rate. (Lehr, Jay; Combined Media Report (34).

2. There is no chemical change in the leachate as it migrates through the aquifer.

3. The unsaturated zone is considered a delay mechanism only.

4. In the saturated zone, the aquifer is uniform and the natural groundwater gradient is constant.

5. Steady-state conditions exist.

This model calculates dilution factors using the following equation:

$$C\ (\text{ground water}) = \frac{IC(\text{leachate})}{I + (UB/L)}$$

where:

C = pollutant concentration

I = leachate infiltration rate

U = groundwater flow rate

B = depth of mixing

L = length of landfill in the direction of groundwater flow (35)

With the use of this equation, assuming average aquifer characteristics and a constant leachate production rate of 0.3 m/annum, dilution factors were calculated for three types of aquifers (Table 4). Results are given below:

Table 4 Dilution Factors For Three Types of Aquifers

Aquifer	Distance from landfill 50meters (164 ft)	300 meters (984 ft)
Chalk	15 - 50	100 - 250
Sandstone	3 - 10	15 - 50
Gravel	100 - 200	200 - 500

The lowest dilution factor obtained by these calculations (3x) was for a contaminant migrating through a sandstone aquifer beneath a landfill 50 m long. A well directly downgradient from the landfill would thus be expected to contain water (landfill leachate) exhibiting this degree of attenuation Any additional dilution that may occur would depend on how fast water was withdrawn from the well. If high pumping rates were employed water from outside the plume might be drawn into the well thus diluting the contaminated water (33).

Existing empirical data (and there is not a great deal) likewise indicates considerable variability in pollutant dilution factors in groundwater. The behavior of chloride graphically illustrates this. The chloride ion is a highly mobile and persistent contaminant. It is readily leached from waste and is resistant to ion exchange, chemical reactions and adsorption. Attenuation of chloride during migration is due to dispersion and dilution. Some observed dilution factors for chloride at various distances from waste disposal sites are listed in Table 5.

TABLE 5. Chloride Dilution Factors (14)

Site	Distance	Dilution Factors
Illinois landfill	650 ft.	4-5
Llangollen, Delaware landfill	650 ft.	27
Connecticut landfill	200 ft.	2
Fly ash settling pond	500 ft.	8-9
DuPage County, Illinois landfill	32 ft.	2
Winnetka, Illinois landfill	800 ft.	13
Tythegston landfill, England	330 ft.	2-3

Attenuation factors for hazardous constituents of leachate also vary widely. Table 6 illustrates data from field analyses of several waste disposal sites.

TABLE 6 - Pollutant Attenuation Factors (14)

Site	Pollutant	From Disposal Site Distance	Attenuation Factor
Iowa landfill	Arsenic	400 ft.	12 - 13
Fly ash settling pond	Arsenic	500 ft.	4
Kings Kettle landfill, England	Cyanide	430 ft.	50
Coatham Stob landfill England	Chromium	500 ft.	100
Mitco	Phenol	adjacent	>23
Mitco	Nickel	adjacent	>170
Mitco	Phenol	adjacent	>1000
Mitco	Zinc	adjacent	>14

The results illustrate the current rudimentary understanding of leachate attenuation and the difficulty in arriving at a dilution factor which reasonably reflects the dilution in concentration from the point at which the contaminated leachate leaves the disposal site to the point of human or environmental exposure. In sum, there exist no widely accepted criteria for gauging this diminution in concentration.

B. EPA'S CHOICE OF AN ATTENUATION FACTOR

In the proposed regulation, EPA chose a dilution factor of 10 as a conservative, but reasonable figure. EPA based

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this dilution factor on (1) the figures computed from the mathematical model--figures which incorporated EPA's original assumptions of no attenuation between waste matrix and groundwater aquifer, and, (2) the empirical analyses of attenuation experienced at actual landfill sites. EPA does not believe that this factor of 10 represented the minimal level of dilution that could be expected. For instance, leachate migrating from a disposal site in Islip, New York was not attenuated by that amount until it had migrated 805 meters (0.5 mile)(28). It did, however, believe that a dilution factor of 10 provided a reasonable degree of protection to the public health and the environment while at the same time acknowledging the broad range of hydrogeological conditions at waste disposal sites across the country and the variety of contaminants likely to be released.

A large number of comments were received concerning the proposed dilution factor. Most argued that the factor of 10 was arbitrary and far too conservative. Others argued that the factor of 10 was not conservative enough and that only a factor of zero would ensure adequate protection to public health and the environment.

EPA has carefully reevaluated its original choice of a 10-fold dilution factor and has decided that a 100-fold dilution factor would be more appropriate. A number of considerations have motivated EPA to make this alteration.

Probably the most important consideration is the relative absence of empirical data upon which to base an attenuation factor, and strong suggestions that choice of any of a wide range of attenuation levels could be supported by what data is available. This absence of empirical data is particularly troubling because the dilution factor plays an exceptionally important role in defining the breadth of the EP's coverage.

A second consideration involves a shift in current regulatory strategy. The EP was initially viewed as the principal mechanism for bringing hazardous wastes into the Subtitle C regulatory system. However, when it proved impossible to develop suitable characteristics for carcinogenicity and other aspects of toxicity, (see pp. 12-18 above), the Agency decided, at least for the present, to use the listing mechanism as the chief means of coverage. The overall scope of coverage of the EP thus became somewhat less critical, and a less conservative attenuation factor more appropriate (particularly since the listing mechanism encompasses wastes containing EP contaminants).

Another consideration is the absence of a variance procedure for wastes which exhibit the property of EP Toxicity (i.e., wastes which fail the EP are conclusively deemed to be hazardous). The effects of a waste being anomalously brought into the system by the EP are greatly aggravated by this lack of a variance procedure, thus dictating the need for some caution.

A further consideration is that the EP is a necessarily less precise instrument than the flexible listing procedure for determining whether a waste which straddles the line is in fact hazardous. For instance, the EP fails to take into account the quantity of a waste generated--a factor which could make a difference in determining whether a marginally hazardous waste belongs in the system or out. Similarly, the EP fails to take into account mismanagement scenarios specific to the waste which might argue for including the waste in the system even though it passed the EP. Consequently, EPA believed that marginal determinations of hazard might better be entrusted to the listing mechanism.

EPA is also concerned that its assumption of zero soil attenuation may have been unduly conservative, since soil attenuation may play a role in many waste management situations. A decision to take soil attenuation into account also suggests some need to increase the attenuation factor.

EPA has therefore decided to adopt a 100-fold factor. It is convinced that waste which fails the EP at the 100-fold factor has the potential to present a substantial hazard, regardless of the waste's management circumstance, so that coverage will certainly not be over-inclusive. In order to bring into the system wastes which present a potential substantial hazard but do not fail the EP at the 100-fold dilution factor, EPA has listed and will continue to list wastes which do not fail the EP at this 100-fold factor. Its adoption of the 100-fold factor will thus shift to the listing mechanism some of the burden for capturing wastes containing EP contaminants.

EPA emphasizes that the change to the 100-fold dilution factor is provisional. If forthcoming studies demonstrate that another attenuation factor is more appropriate, EPA will switch to that factor. In taking the cautionary step of moving to the 100-fold factor, EPA recognizes it is empowered to forge ahead in the face of scientific uncertainty. By the same token, however, it is empowered to act cautiously--especially when there is another means (here the listing mechanism) of accomplishing its goal.

The Agency is cognizant of the fact that for four of the organochlorine compounds for which thresholds have been established, the threshold exceeds the published water solubility for the compounds. However, the Agency does not believe this presents a problem.

The primary purpose of the EP Toxicity Characteristic is to identify manufacturing or process wastes containing leachable contaminants in toxicologically significant levels. When present in process wastes or as formulated products, the compounds are normally present in admixture with other organic compounds which tend to act as cosolvents to increase the apparant water solubility. Thus the Agency believes that the water solubility is not a true measure of potential solubility in the EP extract.

A second factor leading the Agency to conclude that this potential problem may not be a serious one relates to the specific pesticides involved. Several of them enjoy only limited use and thus are unlikely to actually be present in any significant number of wastes.

However, the Agency is studying this apparant problem and if it is determined that corrective action is needed, such changes will be incorporated into future revisions of the regulations.

V. RESPONSE TO COMMENTS RECEIVED ON THE PROPOSAL AND ON THE NOTICED REPORTS

A. Adopt Existing Regulations

The Agency received several comments questioning EPA's need to develop a new method of identifying toxic wastes since there are already a number of states with regulations which address this problem. These states include Washington (39), California (40), and Minnesota (41). Some commenters specifically suggested that EPA model the Federal regulations on the California and Washington regulations.

The Agency believes that the hazard posed by a waste is primarily dependent both on the intrinsic toxic properties of the waste constituents and the propensity of constituents in the waste to migrate from the waste to the point of environmental exposure. Except in the case of direct discharge to sewers or surface water bodies, contamination of ground and surface water appears to be a function of not just what is in the waste, but also the likelihood of the toxic constituents migrating from the point of disposal. Therefore, in formulating its leaching test, the Agency has attempted to comprehensively incorporate into the test consideration of the waste's migration (i.e., leaching) potential. Inasmuch as many of the outstganding state regulations fail to give consideration to migration potential, EPA has not adopted their approaches in constructing the EP.

EPA has, however, to some extent based its listing approach states whose regulatory approaches most resemble EPA's in this regard are Minnesota and California. In both the Minnesota and California approaches, wastes are considered to be hazardous based on the presence in the waste of a designated toxic specie (40,41). In the Minnesota regulations, the waste must contain a given concentration of the toxic species. In the California regulations, the mere presence of any one of a long list of chemical species is presumed to make the waste hazardous, unless the generator proves otherwise. EPA's newly formulated criteria for listing come very close to incorporating this California approach. Under these criteria, the presence of a hazardous constituent is deemed to make the waste hazardous unless the Administrator, after considering any of a number of factors concludes that the waste is not hazardous. Most of these factors have a direct bearing on migration potential.

EPA has elected to adopt this approach in the Extraction Procedure Toxicity Characteristic in recognition of the differences between the two mechanisms. The EP Toxicity Characteristic is a one-shot mechanism for bringing wastes into the system; there is no opportunity for generators to present mitigating data nor is there any variance procedure. Consequently, it is incumbent on the Agency to fully incorporate consideration of migration potential into the test protocol accompanying the characteristic. The listing mechanism, on the other hand allows for some generator input into the

Agency's determination and is accompanied by a variance procedure. Consequently it is permissible to create what is in effect a presumption for listing based on the mere presence of the toxic constituent in the waste (as California does (40)), in view of the opportunities provided for subsequent consideration of migration potential and the opportunities for more individualized consideration of hazard.

B. Suitability of EP As a Regulatory Tool

A number of comments were received concerning the suitability of using the Extraction Procedure as a regulatory test. These comments, many of them similar, addressed the reproducibility, validity, accuracy, and scientific defensibility of the procedure. The comments came from all factions of the affected community including industry, government, environmentalists, academia and citizens in general.

The comments addressed one or more of the following five areas:

1. Appropriateness of using a single test procedure, based on a single model of assumed management, to determine the hazardous potential of wastes which are disposed of in a wide variety of disposal environments.

2. Acceptability of using for regulatory purposes a test procedure that has not been fully accepted by the scientific community.

3. Whether the EP is reproducible enough for it to be acceptable for regulatory use.

4. Accuracy of the Extraction Procedure.

5. Propriety of having a hazardous waste definition employ a test procedure which requires the exercise of scientific judgement.

1. Appropriateness of Using a Single Test, Based on a Single Model of Assumed Mismanagement, to Determine whether a Waste is Hazardous

The vast majority of comments revolved around the Agency's use of a single test procedure, based on a single model of assumed mismanagement, to determine whether a waste is hazardous. Many of these comments specifically questioned the appropriateness of the Agency's utilization of a co-disposal scenario. Others expressed the view that because they handle their waste in a manner very different from that described in the scenario on which the Extraction Procedure is modeled, the EP should not apply to them and a means should be given to permit them to disprove the results of the EP. Some commenters were especially critical of the Agency's use of one test to measure environmental mobility in light of the comments expressed by Ham et. al. (14,16). Some specific statements of Ham that were pointed to are:

> "A standard leaching test provides a reproducible set of numbers that are a function of the interaction of waste with a specific leaching solution under a specific set of conditions. It is up to the decision maker to evaluate those numbers and make a prediction regarding the behavior of the waste in a landfill. Unfortunately, the multiplicity of factors affecting the leaching characteristics of a waste, both in the test and in the landfill, and the variability of landfill conditions, dictate that interpretation be done with care and with consideration of the waste and landfill characteristics. Test results should not be interpreted rigidly, e.g., developing criteria stating that a certain concentration of a given parameter in the test leachate automatically and without further consideration indicates that the waste is hazardous in the landfill. Rather, consideration should be given to such factors as the amount of waste to be disposed, the annual net infiltration of water in the area of the landfill, the factors affecting the leaching of the waste (as far as can be determined from the test results), possible waste-leachate interactions, and the fate of the landfill leachate after it leaves the waste and passes through wastes or soil."(16, p. 3,6)

"Because of the major differences in a waste's leaching characteristics as a result of the leaching media composition, no one media can give results adequate to describe properly the leaching characteristics of a waste." (14,p.2)

"The importance of using different leaching media was indicated by the results." . . . "Without the use of several leachates, test results could be very misleading and have no relation to the actual landfill for a particular waste." (16, p.2)

Proper interpretation of the results from the recommended procedure is critical to its usefulness. The test was designed to be aggressive; the numbers obtained are expected to be maximum values which will not be attained normally in an actual landfill." (14, p.3)

"Whatever standard test is used, interpretation of test results is the crucial factor in determining the test's ultimate value in predicting whether a waste is hazardous when placed in landfill. Virtually any leaching test which is properly interpreted would be more useful in making such a prediction than would be a well designed leaching test which is poorly interpreted." (16, p.7)

"Unfortunately, the multiplicity of factors effecting the leaching characteristics of a waste, both in the test and in the landfill, and the variability of landfill conditions dictate that interpretation be done with care and with consideration of the waste and landfill characteristics. Test results should not be interpreted rigidly, e.g., developing criteria stating that a certain concentration of a given parameter in the test leachate automatically and without further consideration indicates that the waste is hazardous in the landfill." (16, p.6)

"One obvious way to interpret the leachate composition results is to compare the concentrations of the various chemical species to some standard, for example, drinking water standards. This is dangerous, however, and is difficult to defend for the leaching test developed in this study." . . . "It was not designed to provide realistic concentrations of the various species for a specific situation." (14, 127)

"Thus, once a standard leaching test has been designed, interpration of the test results becomes a crucial factor in determining the applicability of the test." . . . "It is up to the decision maker to evaluate . . . and make a prediction regarding the behavior of the waste." (16, p. 3)

> "It may be possible to correlate test conditions with landfill concentrations by running extensive verification tests, correlating a waste's behavior in the test with the behavior of the same waste in a carefully monitored landfill. Correlation coefficients could then be developed for parameters and conditions similar to those in the verification study and the test result used to estimate landfill concentration." (Background)(14, p. 124)

> "There is a lack of data regarding leachate generation at fullscale industrial waste landfills with which results from the laboratory leaching procedure can be compared. Field verification studies are needed in which unattenuated and indiluted leachate from specific industrial wastes in mono- as well as co-landfill situations can be compared with appropriate leaching test results, preferably on a long term basis." (Background)(14, p.4)

As was discussed earlier in this document, EPA believes it has the authority to base the EP Toxicity Characteristic on a single plausibly-occurring scenario of mismanagement even if this mismanagement scenario does not precisely correspond to the circumstances of a particular generator's management practices. Those who quoted Ham on this point failed to appreciate that Ham's goals differed somewhat from the Agency's goals. Ham was interested in designing a test which, insofar as possible, evaluated the leachability of particular wastes as they are actually managed in particular landfill environments. Recognizing that the leachability of a waste, and thus its ability to cause a hazard, is a situation-specific phenomenon, Ham counseled caution in applying the results of the test to specific landfill situations. EPA, on the other hand, is not as interested in the leachability of a waste as it is actually managed as it is in the leachability of the waste under some plausibly-occurring mismanagement situation. Thus, while EPA recognizes that its test will not predict the leachability of particular wastes as they are actually managed,

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it believes that its test is reasonably predicitve of the hazard which a waste could present if *mismanaged*. EPA has intentionally refrained from making its definition of hazard dependent on the actual management to which a waste is subjected, because it believes that the Act contemplates defining hazard in terms of some assumed level of improper management. Making the definition of hazard completely dependent on situation-specific management practices would have the effect of excluding from the hazardous waste management system those wastes which are properly managed, with a consequent sacrifice of the continuing oversight and assurance of proper management provided by the system.

The above does not, however, fully respond to those who argued that, in constructing its scenario of assumed mismanagement, EPA should to the extent possible take into account the actual *mismanagement* practices to which particular wastes are likely to be subjected. One of the principal comments along this line was that EPA should use a variety of leaching media in the EP to take into account the fact that many wastes are not likely to be disposed of in municipal landfills, even if improperly managed.

The Agency recognizes this concern but believes, as articulated in greater detail above, that the single leaching medium it has elected to employ, when considered in light of the other aspects of the test, is reasonably predictive of the the leachability of mismanaged wastes, even if those wastes are not disposed of in municipal landfills. The Agency also believes that its decision to employ a single model of improper management is justified by concerns about the administrative feasibility of employing more sophisticated multiple models. In any event, to the extent the commenters are concerned that, by failing to tailor the model of improper management to specific management conditions, EPA is making its test too aggressive, these concerns are put to rest by EPA's switch to the 100-fold dilution factor. EPA is fully convinced that anything which fails the EP at the 100-fold factor has the potential to cause a hazard, no matter what leaching medium, etc., it is actually exposed to.

2. Acceptance by Scientific Community

A number of comments questioned the acceptability of using a test procedure which has not fully been accepted by the scientific community. Before addressing the acceptability of using a test procedure for regulatory purposes that has not been fully accepted by the "scientific community," one must first define what is meant by the "scientific community".

There are two groups making up membership in this community; those scientists working for industry, government, and other entities who will be directly affected by the regulations and scientists whose only interest is academic. The first group has a direct financial or institutional interest in seeking to exempt from the system waste(s) their organization or constituency generates. Obviously, these members of the regulated community are concerned with the economic implications of any test methodology employed in defining a hazardous waste. The second group of scientists are basically motivated by a desire to assist the Agency in developing regulations utilizing the "best" information that the scientific community possesses.

In the main, it was the regulated community that commented that methodology should receive scrutiny and acceptance by the "scientific community" prior to regulatory use. The Agency agrees with this comment. Toward this end, EPA developed the proposed test procedures in open view of all interested parties in hope that scientists would then

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apply the procedures being developed to wastes of concern and, with the data so obtained, assist the Agency in correcting any problems with the proposed procedures. With few notable exceptions (35, 37, 42, 43) this did not happen. Scientists from the regulated community have, in the main, concerned themselves with trying to convince the Agency to modify the test procedures. Their goal was to make the test procedures less aggressive and, thus, less likely to identify their particular waste as a hazardous waste, rather than to determine if the procedures were scientifically valid (i.e., accurately identify wastes needing controlled management). Even though the Agency extended the comment period on March 12, 1979, for an additional sixty days (44 FR 13548)(44), industry did not submit significant amounts of data.

While many comments were received commenting on the invalidity of the test procedures, few commenters supplied the necessary scientific data to justify their concern. The chemical industry was especially unresponsive. Studies sponsored and conducted by the Agency(18,19), the Electric Power Research Institute(37), and others (35,36) have indicated that the Extraction Procedure is of acceptable reproducibility for regulatory use. Given the lack of convincing data to the contrary from the affected groups, the Agency has decided to employ the Extraction Procedure in the regulations being promlulgated today. If future research uncovers better test procedures for use in §3001 regulations, the regulations will be amended.

Some commenters expressed the concern that the procedure was adopted without thorough consideration of other available leaching test methods. Similarly, commenters expressed the view that there have been several radically different versions of the Extraction Procedure issued by the Agency and that, as a consequence, EPA lacked testing and evaluation data on the specific procedure that was proposed.

As is discussed in earlier sections of this Background Document, there has been a considerable amount of research conducted by or on behalf of the Agency leading up to the finally promulgated test procedures. Included in this research was a study of existing leaching methods by the Mitre Corporation (15), the Ham studies aimed at the development of a standard leaching test (14,16), the extensive work conducted at the Oak Ridge National Laboratory (7,19,24), and the work done under the direction of ASTM's Committee D19.12(14). In addition, EPA published a number of drafts of the various test procedures being studied by the Agency in order that informed comment could be obtained from the scientific community.

At the time of proposal, data on the Extraction Procedure was admittedly less than desirable because the final steps in validating the procedure for regulatory use were not then completed. This deficiency has been to a large extent corrected by studies conducted on the test as finally promulgated.

3. Reproducibility of the Test Procedures

A number of commenters argued that the EP was not sufficiently reproducible for use in a regulatory framework, and at least one commenter argued that the accompanying analytical procedures were also not sufficiently reproducible. Many of these commenters based their arguements on five separate research studies which have examined the reproducibility of the EP and the analytical techniques employed in analyzing the extracts for their hazardous constituents (35,36,37,19,18). The issue these commenters addressed was whether the EP is an accurate simulation of real environmental processes and not the issue of the adequacy of the EP and the analytical procedures to produce relatively consistent results when repeated trials are run on a given waste sample.

In responding to these commenters, it would be helpful to review the results of the five studies and assess their implications for the reproducibility of the EP. Before doing this, however, two things should be noted. The first is that there is no consensus on what constitutes an acceptable level of reproducibility, nor did any of the commenters indicate what an acceptable level would be. Any analytical procedure or test produces variable results, especially state-of-the-art techniques such as the EP. A strong arguement can therefore be made that a procedure is acceptable, whatever its statistical reproducibility, as long as it is logically reproducible - - i.e. as long as the procedure is capable of actually being performed on waste samples without operational

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obstacles. The second thing that should be noted is that greater reproducibility can always be obtained by running further replicates of the procedure -- an operation that tends to decrease the size of the confidence interval and thus ensures greater certainty in the results. Lack of reproducibility can also be corrected by isolating the causes of the lack of reproducibility and altering the procedure accordingly. Absence of reproducibility is thus a correctable rather than an absolute infirmity. In recognition of this, the Agency intends to provide advice to generators on the number of replicates of the EP which can be run to ensure confidence in the results. Additionally, EPA is engaged in ongoing research studies to isolate and eliminate the causes of any variability in the EP and accompanying analytical procedures.

The five studies (35,36,37,18,19) mentioned above, which examined in some way the reproducibility of the EP and the accompanying analytical procedures, shed light on the question of reproducibility but provided no hard and fast conclusions. These studies are hampered by a number of problems. First, the studies have not been designed to differentiate between the reproducibility of the EP and the reproducibility of the analytical techniques. The only exception to this is the study conducted by the Electric Power Research Institute (EPRI)(37). Second, the studies, as a general matter, fail to fully differentiate between intra-laboratory reproducibility (consistency) and inter-laboratory reproducibility (concurrence) even though intra-laboratory reproducibility (consistency) is probably more germane to the issue of the adequacy of the EP and the analytical techniques. Third, the studies were not designed for comparison with other studies. Thus, even when results are presented on similar phenomena, e.g., the intra-laboratory reproducibility of analyses results for barium and chromium, the statistics reported are not always sufficient to make good comparisons. For example, some of the studies (19,18) use coefficients of variations (the same as the relative standard deviations, RSD) to indicate the degree of variability in the measures, while others (36) use a relative standard error (RSE). Thus, when the specific means and standard deviations are not reported, it is not possible to calculate uniform measures of reproducibility that can be used across studies.

Fourth, none of the studies were designed to focus specifically on the questions of reproducibility. The exception might be the complex design in the study conducted by the Electric Power Research Institute (37), but the use of geometric analyses makes the study incompatible with research results in the other studies. Also, no interpretation of the results from this study (37) are offered in the report which was available. Along this line also, none of the studies presented data on analytical technique reproducibility for all of the toxic metals included in these regulations. This leaves open the question of whether different levels of reproducibility are characteristic of different toxic metals. This limitation is important because it cannot be assumed that the analytical precision of measures on one element could be equally precise for another element.

Apparent Reproducibility of the EP

With the above in mind, we turn to a review of these studies insofar as they bear on the reproducibility of the EP. The study by the American Electroplating Society (35) examined twelve wastes (sludges) generally representative from wastewater treatment systems in the electroplating industry. The study as a whole consists of thirteen experiments, some of which are still in progress. Two major deviations from the EP were incorporated in the study. First, lumps of solids in the waste samples were broken up by stirring prior to the initial centrifugation or filtering of the sample. As stated in the report, this stirring could possibly cause a higher level of toxic metals in the final EP extract (35, p.2-2). The second deviation from the EP was involved when, after agitation, the beakers with the solid waste material were removed, covered with a parafin cover, and allowed to stand and settle overnight (35, p. 2-4). Both of these deviations from the EP standard invalidate any good estimate of the general reproducibility of the EP. It was noted in the report that filtering vs. centrifugation in the EP can make the difference between passing or failing the threshold values for toxic metals established by the EPA (35, p.2-5). However, the experiment involved only two metals, lead and chromium, and two levels of pH, pH 5 and pH 7. At the specified pH 5 level in the EP, the threshold value for lead was surpassed when centrifugation was used to separate the solid material from the sample. The threshold value was not reached when filtration was used.

The NUS Corporation (36) subjected samples of four waste materials to the EP and analysis using the AA techniques. Few comments in the report related specifically to the reproducibility of the EP, except that the specified EP was used. The NUS study also compared Toxic Extraction Procedures (TEP) with the EP. The TEP is the precursor to EPA's current EP. One statement from the NUS report (36), however, deserves special comment. The report states that sampling error is a factor in the (inter-laboratory) reproducibility test. Even though the report makes the distinction between "repeatability" (intra-laboratory consistency) and "reproducibility" (inter-laboratory concurrence), the statement is not appropriate if aliquots of the same EP extract are used. Specifically, sampling error relates to the overall representativeness of the waste material to be characterized, not to the precision of the EP or of the analytical techniques.

The Oak Ridge National Laboratory (19) employed the EP and analyzed eighteen different wastes, including arsenic-contaminated ground water. The standard EP was followed, except that extractors made of different materials or combination of materials were used. The report states that "no significant problems were encountered in extracting or analyzing wastes for inorganic species"(19, p.2), but several suggestions were offered with regard to various aspects of the EP. For example, stirring problems, e.g., binding and sampling grinding, were encountered with some of the wate material during extraction.

Also, the report recommended that a nonmetallic extractor should be used to lessen the possibility of contamination occurring during waste extraction. In general, however, this report (19) suggests that the EP is relatively reproducible. One statement (19, p.15) suggests that reported values of chromium, nickel and calcium indicate an EP variability trend that exceeds that expected for analytical determinations. This statement applies only to the situation when extractors made of different materials are used. Out of context, the statement would suggest that the EP is unreproducible in either intra- or inter-laboratory stiuations.

A total of twenty-five wastes from eleven different sites were examined in the study by Environmental Monitoring Systems Laboratory in Las Vegas (18). One specific deviation from the EP was employed in the study. All waste materials were screened by inductively coupled plasma emission spectroscopy (ICM) to select those wastes for EP and analyses by AA methods (18,p.22). Also, different kinds of agitation, the wrist-arm shaker and the extractor device, were used in the study. The report states that preliminary results suggest good agreement (from the analyses) between the two types of agitation. Like the Oak Ridge National Laboratory Study (19), this study (18) also suggests that steel containers not be used in the EP because of its possible contamination in tests for chromium. Also, the report states that the variation in the tests for barium are due to the analytical method (not the EP). Other studies are planned which will address the issue of the reproducibility of the EP more directly, but there is little in the interim report to suggest that the EP is not generally reproducible.

Finally, the study by the Electric Power Research Institute (37) is the only investigation which clearly separates out the question of reproducibility of the EP and the analytical techniques. Further, the complex design partitions (through analysis of variance (ANOVA) techniques) variation of the EP and analysis techniques which can be attributed to inter- and intra-laboratory results. Four types of utility wastes were subject to the EP and analyzed in the study. The design included all the toxic metals except silver. Also, the basic design of the study was intended to compare flame and furnace AA methods of analysis. Unfortunately, because of incomplete data and values for toxic matal content which were sometimes below detection limits, a variety of adjustments were incorporated into the overall statistical analyses. For example, simulation methods were used to produce enough observations to complete the ANOVA design. Geometric techniques were employed because of the highly skewed observations, i.e., results from the test of toxic metals in the waste materials. In all, the results of the study should be given a very conservative interpretation. As noted previously, no interpretation of the results is offered in the study report. However, examination of the data presented and communication with those persons who conducted the analyses suggest two major findings:

First, as might be expected, intra-laboratory reproducibility (consistency) for both the EP and the analytical techniques tended

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to be better than inter-laboratory reproducibility (concurrence). Secondly, the reproducibility of the EP overall (both intra-laboratory and inter-laboratory) appears to be better than the overall reproducibility of the analytical techniques. This latter finding suggests that the overall reproducibility of the analytical techniques may be more of a problem than the EP itself. This is contrary to assumptions which have been made in some studies (36) and further questions the use of the analytical results of EP extracts as an uncontrolled criterion to assess the reproducibility of the EP.

Apparent Reproducibility of the Analytical Technique

Most of the five studies reviewed addressed, to some extent, the general reproducibility of the analytical techniques. The data reported, however, is sometimes too incomplete to make any comparisons among the different studies. Consequently, caution has to be exercised in generalizing about the reproducibility of the analytical techniques. Some discussion about the statistical measures used to indicate reproducibility is in order before proceeding to the separate research studies. The measures mentioned or employed across the studies have included the following:

- standard deviations
- relative standard deviation, i.e., the standard deviation expressed as a percentage of the mean
- the coefficient of variability, i.e., the same as the relative standard deviation
- the range of values, i.e., the difference between the

highest and lowest value

- standard error (unspecified), and
- relative standard error, i.e., the standard error of the mean expressed as a percentage of the mean.

Each of these measures can be used to assess relative reproducibility under certain circumstances. In some cases, however, the measures can be misapplied. For example, the best indicator of reproducibility when replications are made of the same test and the values are averaged is the standard error of the mean or the relative standard error, not the coefficient of variability, i.e., the relative standard deviation. The advantage of the standard error of the mean is that probability statements can be made about hypothetical true values, e.g., the threshold values, or different mean values obtained from other tests of the same waste material. The only study to employ the standard error of the mean (specifically the relative standard error) was the NUS Corporation study (36). The relative standard error (RSE) indicates that one can be 95% confident that the true value, e.g., level of toxic metal, is within ±1 RSE of the mean value obtained. There is no direct way of comparing the coefficient of variability and the RSE. The advantage of the relative standard deviation or the relative standard error is that variation is expressed as a percentage of the mean, thereby facilitating relative comparisons of the variation around the mean, i.e., reproducibility.

The study by the American Electroplating Society (35) presents data on the intra-laboratory reproducibility (consistency) of duplicate analyses for three wastes on toxic levels of cadmium, lead and chromium (35, p. 2-20). The results for lead are probably not representative since the values for lead content were near or below the detection limits of the analytical technique. The other results of the analyses of the extracts at pH 5 are presented below in mg/l:

Waste	Cadmium			Chromium		
	Mean	SD	RSE	Mean	SD	RSE
2	120	6	± 7%	3.3	1.4	± 60%
7	1.7	.45	± 38%	.33	.09	± 39%
9	- -	- -	- -	.40	.08	± 28%

The RSE employed above as the indicator of reproducibility indicates the 95% confidence interval as a percentage of the mean. For example, there would be the probability of only 5 times out of 100 that the true mean for cadmium in waste 2 would be outside of the range of 111.6 to 128.4. The RSE also permits comparisons by the calculation of the 95% confidence intervals for each measure. For example, the 95% confidence intervals on chromium levels in wastes 2, 7, and 9 would be 1.32 to 5.28, 0.20 to 0.46, and 0.28 to 0.512, respectively. Thus, one could say that the chromium level in waste 2 is significantly ($p < .05$) different from the chromium levels in either waste 7 or waste 9. On the other hand, because the confidence intervals overlap, it cannot be said that the chromium levels between wastes 7 and 9 are significantly ($p < .05$) different. Further, it cannot be stated that the chromium level in waste 9 is significantly ($p < .05$) below the threshold value of .50 mg/l proposed in 43 FR 58956(9). However, one can state, with confidence that it is below the threshold value in the final regulations.

Other information regarding the inter-laboratory reproducibility (concurrence) on measures of three elements in solid waste from two plants is presented in the AES report (35, p. 2-21). Samples of the EP extraction of one waste analyzed at three laboratories for cadmium, chromium and lead content show excellent concurrence. Similarly, data on samples of EP extract of waste material from another plant indicated generally good concurrence on chromium and lead, but not mercury. Data was not available in the table (35, p. 2-21) to calculate the RSEs, but the values presented in the tables are remarkably close (and in some cases identical) for at least two of the three different laboratories. The above situation provided a rather clear indication of the inter-lab reproducibility (concurrence) of the analytical procedures, since each laboratory analyzed aliquots of the same EP extract.

The Environmental Monitoring System Laboratory study (18) reports some data on the intra-laboratory reproducibility (consistency) of the analytical techniques for barium, chromium and lead in EP extracts from waste in two ponds at one disposal facility. Flame AA analyses were performed in triplicate on each of three aliquots of sample extracts. The RSEs for each of the analyses ranged from ± 1% to +36% for barium, chromium and lead. Significant differences ($p < .05$) were found between EP extracts from the two ponds, but not within the analyses of the three aliquots of each EP extract. In all analyses for

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chromium and lead, the RSE was below ± 3%. The reproducibility results (RSEs) for barium were less stable (ranging from ±1% to ±36% with an average intra-laboratory analysis reproducibility across both ponds of ±17.2%.

The study by Environmental Monitoring Systems Laboratory (18) used ICP screening to select the twelve sample wastes (two of one waste) for EP. Using the threshold values for barium, chromium and lead as the criteria for comparing results of the ICP and the EP extract analyses, the results at or above the threshold were confirmed by the EP extract analyses in five cases, but not confirmed in six cases. Under "worst case" conditions of waste samples described in the report, five of the eleven wastes exceeded the threshold values for either barium, chromium or lead. Further experiments to evaluate the analytical procedures are underway, but the report (18) offers some tentative conclusions about the reproducibility of the analytical methods -- namely, analytical methods for chromium and lead were found to be highly reproducible (consistent). Also, either the EP and/or the analytical method for mercury may not identify the presence of mercury in waste (18), p. 35).

The NUS Corporation report (36) presents some intra-lab reproducibility (consistency) data for the analytical results of EP extract from four wastes shipped from nine different laboratories (36, p. 32). A synthesis of the data presented in Table 3 (p.32) of the report is presented below for analyses which were completed, i.e., results were definitive and not expressed as less than a certain value (ppm).

Sample	Element	Mean	SD	RSE
Fly Ash	Arsenic	.227	.226	±66%
	Chromium	.08	.032	±27
BOF Slag	Lead	.441	.107	±16
Refinery Sludge	Arsenic	.017	.006	±24%

These results indicate moderate intra-laboratory reproducibility (consistency) for four of the elemental analyses conducted on three types of solid waste EP extracts.

The study conducted by Oak Ridge National Laboratory (19) presents some data on the intra-laboratory reproducibility (consistency) of analytical techniques on a variety of EP extracts of waste. However, not enough information is provided to estimate the variability or estimate reproducibility since only mean values or single determination values are presented (19, p. 37).

Finally, the general results regarding the apparent reproducibility of analytical techniques in the Electric Power Research Institute study (3) have been presented previously under the discussion on EP reproducibility. Since the results in the study are presented within an ANOVA design, it is difficult to assess the different aspects of variability except in relation to each other. Also, examination of the 90% Confidence Multipliers (CMs) shows mixed results on inter-lab analysis variability and intra-lab analysis variability according to type of analyiss and type of toxic metal. For example, the CMs for inter-lab analytical variability on page 14 of the report (37) range from 1.01 to 13.02. The CMs for intra-lab variability are generally less, but range from 1.01 to 1.41. These ranges exclude analyses where "the number of values reported as 'below the detection limit' was not so large as to preclude statistical analyses, but large enough to make the results less reliable" (3, p. 3 of Phase I Report). The effect of the simulated values on the CMs is not known exactly. Consequently, only tentative conclusions, or hypotheses, about reproducibility seem justified from the report.(37)

In conclusion, the above reports, while not complete enough to permit any firm conclusions, do contain data which is suggestive on the issue of reproducibility. Of particular interest is the suggestion in the EPRI data that the EP is at least as reproducible, if not more reproducible, than the analytical techniques. In as much as these analytical techniques have generally been accepted by industry and others as being sufficiently precise for regulatory use, the EP should also prove acceptable.

4. Accuracy of Test Procedure

A number of commenters questioned whether the EP was sufficiently accurate for use in a regulatory regime. By this they apparently meant one of two things: either that the EP inadequately predicts the leaching which might occur under the disposal conditions postulated in the EP's definitional model or that the EP is not sufficiently precise to enable one to be confident in the results obtained from a given testing.

In response to the first criticism, the Agency believes, based on its hypotheses noted above, that the EP (not including the attenuation factor) is an accurate prediction of the levels of leaching which could occur in a relatively aggresive leaching environment. The Agency concedes however, that it may have fallen somewhat short of fully modeling the leaching which could occur in a actively decomposing municipal landfill--in part, bacause its leaching medium fails to take into account the various chemical, biological and physical factors which bear on the aggressiviness of municipal landfill leaching media. The Agency further concedes that it had little empirical data upon which to base its assumptions about the accuracy of leachability on site specific considerations. Obtaining such empirical data may be an ephemeral goal. Nevertheless, the Agency hopes to assemble data on leachate concentrations observed at actual landfill sites in an attempt to gauge the representativeness of the EP.

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In response to the second criticism, the Agency believes that the EP is sufficiently precise to enable one to obtain reasonable confidence in the results of the test--especially given the fact that one can always obtain greater confidence in the results by running further replicates of the test. The width of the confidence interval has an inverse relationship to the number of tests run on a given sample. Consequently, if there is a question whether a given test is reflective of the "true" result, it becomes a simple matter to run additional samples until the desired confidence is obtained.

5. Propriety of Requiring Exercise of Scientific Judgement

A number of comments argued that the Extraction Procedure, as published in 43 FR 58956(9), was not well enough defined to permit the unambiguous interpretation of how the procedure should be followed. Furthermore, problems arose in conducting the liquid-solid separation and in agitating the sample during the extraction phase of the procedure.

The Agency agrees with these comments and has taken steps to eliminate the difficulties. Some of the specific changes that have been made relate to:

1. specification of filtration as the final stage in sample preparation prior to measurement,
2. specification that the purpose of centrifugation is to aid in liquid-solid separation, not as the final means of separation,
3. use of a generic specification of the agitation equipment
4. codification of under what conditions the sample contains so little solid that it can be considered to be a liquid for testing purposes.

In addition to changes that have been made in the procedure description* the Agency is making available to the public a methodology manual (27) to present additional descriptive information on the sampling and testing methodologies used in the evaluation of wastes. The purpose of this manual is to give more specific operational information than would be practical to put in the regulation itself.

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* Appendix II of the §3001 regulations.

This manual will contain information about testing specific wastes, including clarification of any procedural steps needed to correct interpretational difficulties. The Agency intends to keep the manual current by updating it on a regular basis.

However, the Agency believes that no laboratory procedure for waste testing can ever by written that unambiguously addresses all potential interferences. The testing methods have been written for use by experienced scientific personnel. It is felt that such persons will be able to overcome potential problems and obtain acceptable data, given an adequate understanding of the intent of each phase of the testing procedures.

Specific examples of how this philosophy would work can be gleaned from an examination of some of the comments. One organization subjected oak and maple leaves to the Extraction Procedure and experienced significant difficulty in attempting to separate the extractant liquid from the leaves. The intent of the liquid-solid separation step is to remove all particles of the extracted sample having a particle size greater than 0.45 micrometer from the extract. Thus, an experienced scientist would know to allow the leaf particles to settle, under the influence of either gravity or centrifugal force, decant off and filter the bulk of the liquid, then transfer the remaining mass of leaves to the pressure or vacuum filter for removal of the small amount of free liquid that remains. This change, though not significant from the standpoint of the final results, would have eliminated the long filtration time experienced by the commenter.

A second example which serves to illustrate this point relates to the large number of comments the Agency received on the agitation apparatus described at 43 FR 58961. These comments concerned problems with the specific extractor described in the proposed regulations. These problems consisted primarily of jamming when an attempt was made to extract hard, granular wastes, and potential extract contamination caused by using a metallic extractor.

As described in the proposed regulation:

> "A suitable extractor will not only prevent stratification of sample and extraction fluid but also insure that all sample surfaces are continuously brought into contact with well mixed extraction fluid."(9)

The Agency believes that with this description a competent scientist can eliminate any problems, of the above types, encountered with specific wastes or agitators. If the sample is of such a size and consistency that jamming occurs due to the spacing between the extractor blade and the container, then either an agitator with a different spacing should be used or, if this does not eliminate the difficulty, a different type of agitator should be employed. This latter approach was used by several commenters in determining the leachability of

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materials such as coal combustion ash. Though the studies conducted at Oak Ridge National Laboratory (7,19) and Las Vegas (18) indicated that contamination of the extract by an extractor fabricated of Type 316 Stainless Steel was not a significant problem, the Agency feels that if this problem actually manifests itself, scientist conducting the tests will know to employ an extractor fabricated of either plastic or glass, since neither material would hinder attainment of the agitation conditions specified in the regulation.

The most significant problem encountered by commenters in applying the Extraction Procedure to a specific waste, occurred when filtering samples of drilling mud. Due to the thixotropic and pore clogging properties of such materials, neither filtration nor centrifugation was able to effect separation of the liquid and solid phases. It is the Agency's position that, in such cases, the whole waste should be treated as a solid and run through the extraction procedure. If, after performing the extraction procedure, no extract is obtainable, the waste should not be considered hazardous.

C. Failure to Distinguish Between Chromium III and Chromium VI

A number of comments argued that, basing an Extraction Procedure Toxicity threshold on total chromium in the extract was improper*. These commenters argued that the two oxidation states of chromium present very different toxicity and environmental problems and therefore the threshold should be based only on the concentration of chromium in the +6 oxidation state.

In support of this position the following was cited.

- Cr(VI) is significantly more toxic than Cr(III).
- Oxides and salts of Cr(VI) are very soluble in water while those of Cr(III) are relatively insoluble.
- Cr(VI) has been shown to be a potent carcinogen in humans while Cr(III) on the other hand has not been shown to be carcinogenic in either humans or animals.
- Monitoring of groundwater below a landfill receiving tannery waste containing chromium in the reduced +3 state has shown only limited migration after a period of 10 years. (45)
- There is no data to indicate that under conditions of land burial Cr(III) can be converted to Cr(VI).

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* The major group affected by the application of thresholds, appears to be the leather tanning industry. According to a study conducted for the E.P.A.(46) and comments received in response to the proposed regulations(47), the tanning industry generates and disposes of approximately 200×10^6 Kg of waste per year containing approximately 1000 metric tons of chromium.

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In formulating both the National Interim Primary Drinking Water Standards and these regulations, the Agency has chosen not to adopt separate thresholds for the various oxidation states of chromium. The reason for this is the Agency's concern about the possibility of the conversion of chromium from the relatively nontoxic +3 form to the toxic +6 oxidation state after disposal occurs. This concern is based on studies and observations reported by researchers of the California Department of Health (48) and conditions known to occur in municipal waste disposal environments.

A great deal of controversy exists about the environmental and health effects of chromium. The two most important oxidation states of chromium for environmental purposes, are chromium III and chromium VI. There is general agreement as to the hazards posed by the chromium VI state since it exhibits toxic effects to humans and animals by every route of exposure and is reported to be relatively mobile in the environment(48). On the other hand, available evidence indicates a generally low oral toxicity for chromium(III) compounds. The reason for the controversy over the hazard posed by wastes containing Cr(III) revolves around its possible conversion into the more toxic Cr(VI) form under conditions that might reasonably be expected to occur in the environment.

The California researchers(48) found that upon exposure to artificial ultra violet light or sunlight, significant oxidation of Cr(III) to Cr(VI) takes place in water within a pH range of 7 to 10. Exposing an aqueous suspension containing both soluble Cr(III) and precipitated $Cr(OH)_3$, to ultraviolet light and air for 5 days resulted in oxidation of approximately 20% of the total chromium to the Cr(VI) state. After 7 days the percentage of chromium in the Cr(VI) state approached 50% and after 41 days the percentage approached 90%. Definitive evidence of the photo-oxidation of Cr(III) in actual chromium bearing tannery wastes has not been obtained. According to the California researchers:

> "Analysis of these wastes for Cr(VI) has proven unreliable using any of the published methods. These analytical methods all involve acidification of the Cr(VI) solution prior to final analysis because the tannery wastes all contain relatively high concentrations of dissolved organics, and because Cr(VI) is quickly lost by reduction by the organics. We have found that this redox reaction takes place very rapidly and results in irreproducible results for Cr(VI) concentrations. It is commonly held that chromium tannery wastes do not contain hexavalent chromium and the basis for this belief is negative analytical results based on the EPA or Standard Methods procedures(49). Close examination indicates that these negative chromium(VI) data may well be an artifact of the method and do not reflect the true hexavalent chromium content of the tannery wastes."(48)

Given the fact that the oxidation of Cr(III) to Cr(VI) has been demonstrated to occur under relatively mild conditions, and that this demonstration is consistent with the observation that the predominant form of chromium in the surface layers of the sea is the hexavalent form (48), the possibility that Cr(III) in wastes may undergo oxidation after disposal cannot be ruled out.

In summary, the Agency believes that pending further studies to determine the extent to which this conversion does or does not occur under environmentally significant conditions, the only prudent course of action is to consider all forms of chromium potentially toxic. The Tanners' Council of America in their comments on the proposed regulations echoed this conclusion. To quote:

> "A study conducted in California found that ultraviolet light and sunlight promoted the oxidation of chromium. It is appropriate, therefore, that the disposal of wastes containing trivalent chromium be regulated so that these wastes are quickly and adequately covered at the disposal site to minimize their exposure to sunlight."(5)

If future research indicates that such a course of action is not warranted, then the Agency will revise the definition of a hazardous waste accordingly.

D. Operational Problems

Introduction

The comments previously discussed, dealt with what could be termed philosophical disagreements with the proposed toxicity characteristic. In addition to these philosophical questions, a number of comments were received concerning the actual operation of the Extraction Procedure. These comments can be grouped into the following areas:

1. Liquid - solid separation procedures
2. Structural integrity procedure/ Grinding of sample before extraction
3. Problems with the extraction equipment/agitation
4. Adjustment of extract pH
5. Sample: extractant ratio
6. Final volume adjustment
7. Analysis of multiphasic extracts
8. Extractant toxicity as it affects testing of the extract.

This section will address those changes made in the proposed procedure as a consequence of these comments, and explain other suggested changes that were not made.

1. Liquid-solid Separation Procedure

As was briefly discussed earlier, significant problems were en countered by a number of commenters in separating the liquid phase of the sample from the solid phase using either the filtration or the centrifugation procedure. In the case of thixotropic materials such as drilling fluid and paint these difficulties were severe.

As discussed above, the Agency believes that if no liquid phase can be generated using the separation procedure, the whole waste should be treated as a solid and subjected to the extraction. If, after the extraction procedure is performed, no liquid is produced, the waste should be considered nonhazardous.

The separation problems encountered with the wastes other than paint and drilling fluid appeared to be readily overcome using standard laboratory techniques although, possibly because of the manner in which the test procedures were written, the availability of these solutions may not have been readily apparent to the laboratory personnel. In the main, these problems consisted of either clogging of the filter membrane pores or lack of a centrifuge which met the specifications described in the proposed regulation.

In order to overcome these problems, the following changes have been made.

a. The centrifugation procedure is now defined in terms of goals and no specific equipment is specified. This change clarifies the concept that centrifugation is actually more a tool for prefiltration sample preparation than a final separation technique itself.

b. The filtration step is no longer defined in terms of specific equipment. The procedures manual(27) will contain all references to specific equipment to make it clear that specific pieces of equipment are not being mandated. The procedures manual(27) will also clarify for the operator what procedural changes one may make without invalidating the test.

These changes in the description of the filtration step should clear up any uncertainty about the use of vacuum filtration. It is the intent of the Agency that if the solid phase does not require high (75 psi) pressure to affect separation, then use of the more readily available vacuum filter is allowable. The use of the pressure filter offers a means of operationally defining, at what point a wet solid can be considered a solid for purposes of extraction. (For example, when to treat a sludge, though it might actually still contain 85% water, as a solid for extraction purposes.)

The following discussion will address specific criticisms and operational problems brought out in the comments. The first of these relates to the potential clogging of the filter pad by wastes having

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low liquid to solid ratios. This situation may result in a reduced degree of separation and long filtration times. The Agency believes this potential problem is easily overcome. In such cases, if the solid tends to clog the filter pores, an initial centrifugation to compact the solid is recommended. The liquid thus obtained is then filtered to remove carryover particles, and the solid remaining is filtered under gradually increasing pressure. Specific directions will be given in the methodology guidance manual(27) for those investigators unfamiliar with such techniques.

Section 250.13(d)(2)(1)(A)(1) of the proposal(9) called for filtration to continue until no significant amount of fluid (<0.5 ml) is released during a 30 minute period. Commenters felt that for many wastes this is unnecessary. In addition, one commenter, suggested that filtration should be stopped when gas issues from the filter since allowing gas to bubble out of the filter for up to 30 minutes can cause the volatilization of materials from the filtrate.

The Agency agrees with these recommendations and has made the necessary changes in the regulation. In order to eliminate confusion on the part of the testing community without resorting to overspecification, the regulation has been changed to describe what is intended and to delete specification of the filtration time. Laboratory personnel can use whatever filtration time is required for the specific waste. In addition, the final regulation specifies that filtration should stop when gas issues from the filter. This should eliminate any potential problems with gas discharge.

Section 250.13(d)(2)(i)(A)(1) of the proposal(9) called for inverting the filter unit when changing the filter pads. The Agency has been told that filter holders supplied by one manufacturer cannot be inverted without leaking. Thus, the regulations have been changed to eliminate this specification. If membrane changes are necessary to complete the required separation, instructions from the manufacturer of the specific filter holder being employed should be followed.

Some of the commenters reported that when the pressure filtration technique was applied to different wastes, filter cakes with significantly different amounts of moisture were obtained. They felt this indicated a problem with the technique. The Agency disagrees with this interpretation. The filtration procedure is intended to simulate the separation that may occur in a landfill. If the liquid refuses to separate out during pressure filtration, it will also tend not to drain away from the waste when the waste is placed in a landfill.

Comments were received which said that requiring two consecutive 30 minute centrifugations without an apparent change in degree of separation was excessive. The Agency disagrees with this comment but notes that this concern has been accomodated by adoption of the more flexible centrifugation procedure. Because studies indicated that centrifugation alone resulted in carryover of particles > 0.45 um, centrifugation is now simply used as a means of achieving a preliminary separation in order to speed up filtration. All centrates are to be filtered to remove fine particles prior to analysis. This change in the centrifugation procedure addresses the concerns of other comments relating to addressed:

a. Problems with centrifugation of wastes containing solids having lower densities than the liquid phase, and
b. The need to define centrifugation conditions in terms of separation force (g forces) instead of rotor speed and diameter.

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2. Structural Integrity Procedure/Grinding

In order to accomodate generators whose wastes are not expected to undergo significant structural degradation after disposal because of their monolithic structure or subjection to special "fixing" processes, the Agency developed and incorporated the Structural Intgrity Procedure into the proposed regulations(9). This procedure received criticism from several persons and groups. The specific criticisms were:

a. any alteration of the test specimen is not representative of actual field conditions,

b. the specific field conditions used as a model for the Structural Integrity Procedure are completely contrary to conditions that actually exist in the field,

c. the equipment specified in the proposed regulations(9) is unavailable and, thus, industry has not been able to adequately evaluate the procedure,

d. it is impossible to obtain an undisturbed field specimen of the size and shape required,

e. the foam block employed as a sample holder is subject to contamination, and

f. the Structural Integrity Procedure lacks sufficient scientific validation,

Though some of these comments are valid, the Agency does not believe that the information presented in the comments is sufficient to warrant either dropping or substantially modifying the test procedure.

The following states the Agency's reasons for retaining the proposed Structural Integrity Procedure and the reasons why changes have not been made.

None of the comments presented any evidence to support the claim that stabilized, or other monolithic wastes, fail to undergo degenerative structural changes after disposal. In fact, studies (51 and 52) indicate that significant deterioration actually occurs in some cases. One such situation was found to occur with fly ash stabilized with a popular commercial fixation process (52). Thus, the Agency believes that in order to carry out its mandate under RCRA to consider potential for harm under improper management conditions, it is reasonable to extract wastes in their degraded form if degradation is actually going to occur in the field.

A second point raised by commenters concerns the field conditions modeled by the Structural Integrity Procedure. While subjecting stabilized waste to compaction stresses is not routine practice, it is by no means unknown. Advertisements have appeared in a number of publications, including the Washington Post, stressing the beneficial uses to which stabilized waste can be put. Among the uses suggested was as a replacement for gravel in construction applications (e.g., forming bicycle paths). Since such uses are possible, and, in

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the case of some wastes probable, it appears reasonable to assume the waste may be subjected to the compaction forces imparted by earthmoving equipment such as tractors. Given such an assumption, the Structural Integrity Procedure, which is a modification of an established procedure for simulating the effects compaction machinery has on soils, appears to be based on reasonable assumptions.

The comments made with respect to the unavailability of the equipment were due to a misunderstanding on the part of the commenters. The equipment design belongs to EPA, not to any one company. The design and specifications were published at 43 FR 58691(9) and anyone desiring to obtain the equipment could either fabricate it in their own facilities or obtain it from a competent machine shop. EPA published the name of the particular supplier from which EPA purchased its units solely for the convenience of the public.

The Agency agrees with the concern that obtaining an undisturbed specimen of an already disposed of monolithic waste presents a problem. However, the agency envisions preparing samples of the correct size and geometry by casting the fresh waste in a suitable mold, allowing it to cure for the specified time, and then subjecting it to the procedure. This is analogous to the methodology commonly employed in the construction industry for testing the strength of concrete.

For those situations where a specimen is required of an already inplace waste, geological coring equipment (which is inconvenient and potentially expensive) can be employed.

The Agency recognizes the concern with particles becoming trapped in the cellular polyurethane sample holder causing contamination of subsequent samples. To eliminate this potential problem, the equipment specifications have been broadened to permit the use of non-cellular sample holders which are easily cleaned between tests.

EPA believes that even though the reproducibility of the Structural Integrity Procedure has not been determined, the advantages of including the test in the regulations outweigh the potential disadvantages. Elimination of the test would require everyone testing waste to grind it to pass a 3/8" sieve. Retention of the Sturctural Integrity Procedure imposes no additional burden on the regulated community and, at the same time, allows generators who stabilize their wastes against leaching a means of demonstrating this property.

Grinding

A comment was received concerning the fact that some wastes were difficult to grind. The commenter reported that attempting to grind a waste in a blender resulted in the blender breaking. The Agency realizes that some wastes may be very hard. A blender is not designed to be a grinder. If a hard material is to be ground, then equipment designed for such use should be employed. Such equipment is readily available from companies servicing metallurgical and plastics testing laboratories.

In addition, if the material to be tested is so strong that grinding actually presents a problem, then it is likely that such a material would not tend to be ground in the environment and should therefore be evaluated using the Structural Integrity Procedure.

3. Agitation

A number of comments were received concerning problems people encountered, or envisioned, while employing the extractor pictured in Figure 1 of the proposed regulation (43 FR 58961)(9). These comments fall into the following groups:

a. The extraction conditions (40rpm) do not prevent stratification.

b. In certain cases the extractor blade will jam, with the result that the motor can burn out.

c. When using very small samples the top blades do not contact the solution.

d. When solids having a very low density are tested, there is insufficient room in the extractor to accommodate all the solution and still agitate the system vigorously.

e. Use of stainless steel as the material of construction may result in contamination of the extract with various metals.

f. The extractor is not large enough to permit the preparation of sufficient amounts of extract to allow one to conduct the test procedures described in the Advance Notice of Proposed Rulemaking (43 FR 59022)(9).

The Agency recognizes the validity of these comments but believes they are not significant enough to have required a change in the proposed regulation. This conclusion was reached because the regulation, as proposed, incorporated sufficient flexibility to eliminate all these problem areas.

Elimination of these potential problems requires the exercise of scientific judgement on the part of the investigator conducting the tests. The proposed regulation did not specify that any one specific extractor is required. The Agency found that this point was misunderstood by many people. To eliminate confusion a notice was placed in the Federal Register on March 12, 1979 at 44 FR 13548(44). This notice sought to clarify that the Agency's intent in describing the particular extractor was to illustrate one acceptable type of agitator. The Agency did not intend the unit so described to be considered the only one acceptable.

The Agency believes that the specific extractor used in any particular investigation should be determined after considering:

a. the physical characteristics of the waste,

b. the quantity of sample to be extracted,

c. the method of pH adjustment to be employed,

d. the analyses to be performed on the resulting extract, and

e. the number of waste evaluations to be performed concurrently.

Under these conditions, if the analyst is faced with any of the problems previously mentioned, it becomes a simple matter to select an extractor suitable for the waste in question. For example, if a waste is being examined for leachable metals, it would seem prudent to use an extractor fabricated of a nonmetallic material if aggressive conditions are to be employed during extraction. Similarly, if jamming is found to occur, an extractor with either a different blade clearance or one which does not require stirring of the particles should be selected.

4. Adjustment of Extract pH

Two commenters mentioned problems with the pH adjustment during the course of the extraction. The first commenter concerned the potential danger of adding acid to a waste containing cyanide, sulfide, or other constituent capable of forming toxic gas. The second comment complained about the cost of the equipment needed to automate the procedure.

With respect to the danger of toxic gas formation, the Agency believes it is only common sense to evaluate the waste for the presence of gas generation contaminants prior to conducting the Extraction Procedure. This is especially important since the presence of such constituents can make the waste hazardous under the Reactivity Characteristic even if the waste does not contain other extractable toxicants.

With respect to the cost of automating the pH adjustment step, two points need to be made. The first is that automation of the adjustment step is not required by the regulations. Secondly, if a laboratory elects to employ automatic titration equipment, for purposes of saving labor costs, the cost of such equipment is much less than the commenter quoted. Specifically, the equipment described in the proposal, and employed during much of the developmental research conducted at the Oak Ridge National Laboratory, retails for $325 (Cole Parmer Co., Catalog #5997-20) while a similar competing unit retails for $495 (Fisher Scientific Co., Catalog #13-637-650).

5. Sample to Extractant Ratio

One commenter commented as follows:

"The solid/liquid ratio used in the EP test is based on "as received" (wet) weight. This severely complicates intersample and interlaboratory testing. Also, diluting from a ratio of 1:16 to 1:20 requires careful quantitative transfer procedures. Why not just use 1:20 or 1:10, since solid to liquid ratios tend to be arbitrary as shown in the Wisconsin study."

This comment addresses two concerns-problems related to working with materials whose composition may change if care in their handling is not taken (e.g., the wet samples may dry out with a resulting change in percent solid), and the fact that careful laboratory techniques are required throughout testing. With regard to the first point, the Agency has chosen to use wet weight for purposes of computing the solid/liquid ratio because use of dry weight might not prove representative of the leachability of the waste. For instance, if the solid residue obtained after the initial separation procedure still contained a fairly high percentage of liquid, drying the solid residue would dramatically increase the concentration of toxic contaminants in the solid sample with a possible attendant increase in the quantity of contaminants leached from the waste. At the same time drying the solid residue could severely understate the leachability of the waste, as in the case of electroplating wastes. Data

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in the Agency's possession indicates that, for some unknown reason drying electroplating wastes results in lower contaminant concentrations in the leachate (35).

With regard to the second point, the Agency believes that the need for care in performing the analytical transfers does not justify changing the regulations inasmuch as it is in the very nature of analytical chemistry to require such care.

6. Final Volume Adjustment

One commenter suggested that for operational convenience it may be desirable to perform the extract dilution prior to the liquid solid separation step. The following formula for determining the amount of water to add was suggested:

$$V = (20)(w) - (16)(w) - (a)(HOAc)$$

where:

V = ml of water to add

w = weight in gms of solid charged to extractor

a = ml of acetic acid solution added during extraction.

Since this procedural change neither changes the intent nor results of the dilution step, and does save the laboratory investigator time, the Agency has adopted the suggestion and changed the regulations accordingly.

7. Analysis of Multiphasic Extracts

A number of comments were received concerning the analysis of multiphasic liquid extracts. These comments and questions indicated to the Agency that more guidance is needed in this area.

There are basically two methods for handling multiphasic liquid extracts. The phases can be separated, their volumes measured, separately analyzed and then mathematically combined to determine the original concentration for each species in question. Alternatively, the operator can mix the multiphasic mixture, using a high shear mixer (e.g., homogenizer), withdraw an aliquot, then subject the aliquot to a total extraction or digestion depending on the species of interest.

In order to eliminate confusion on the part of the regulated community the Agency has added clarifying wording to the regulation and will give further guidance in the methodology manual(27).

8. Extract Toxicity

A large number of comments expressed concern that the presence of acetic acid, or acetate ion, would interfere with bioassay testing of the extract. This concern is partially valid inasmuch as acetate is known to interfere, in some cases, with the phytotoxicity bioassay procedures currently under development by the Agency (19). However, since the final regulations do not call for any bioassay testing to be performed on the extract, this potential for interference is a moot point. Research at ORNL (7,19) indicates that EP extracts can be evaluated for both mutagenicity and aquatic toxicity without serious interference from the leaching medium. As noted, above, the Agency is continuing work on a leaching medium which will not interfere with bioassay testing.

Some commenters expressed the concern that the acetate would interfere with chemical analysis of the extracts. The Agency knows of no data to indicate that this concern is anything but theoretical and so is not convinced that a change in the methodology is required. If, in the future, there is a demonstration of such interference appropriate changes will be made.

E. Economics of Testing

A number of comments were received on the cost of the test procedures required to be performed by the regulated community. There are two aspects to this concern. The first is the actual cost for performing the specific tests. The second relates to the question of what tests the regulated community will be required to perform on their wastes.

In responding to this comment, it should be noted at the outset that RCRA does not require EPA to take costs into account in formulating its regulations. The Agency believes, however, that the cost of running the EP on one's waste is, by any standard of judgement, reasonable.

The cost of determining whether a waste meets the Extraction Procedure Toxicity Characteristic can be divided into the cost for obtaining the sample and the cost of testing the sample.

Sampling costs are largely dependent on the waste, the generator, and even the plant involved. The Agency believes that it is only right to require one who is disposing of a waste to know what the properties of the waste are. In order to accomplish this one must have a sample of the waste. Thus, collecting a sample of one's waste is not felt to be an unjust burden.

The Agency has found that independent laboratories are quoting prices for testing a specific sample, using the Extraction Procedure and associated analytical procedures, to be in the range of $200-600 for the required tests. These are single sample prices and, for most companies who have several wastes to test, would actually be at the low end of this range (approximately $200).

F. Specific Comments on the Noticed Reports

Since publication of the proposed regulations, the Agency received and made available to the public a number of reports dealing with the development of the Extraction Procedure Toxicity Characteristic. These reports are:

- Compilation and Evaluation of Leaching Test Methods (EPA-600/2-78-095)(15)
- Comparison of Three Waste Leaching Tests (Final and Executive Summary) (EPA-600/2-79-071)(16)
- Toxicity of Leachate, Interim & Final Reports, Oak Ridge National Laboratory(7,19)
- Assessment of RCRA/EP Test Results on FBC Residues: Part II(53)
- Electroplating Wastewater Sludge Characterization, EPA-AES Cooperative Agreement, September 12, 1979(35)
- Evaluation of Solid Waste Extraction Procedures and Various Hazard Identification Tests, NUS Project Number 6745(36)
- Proposed RCRA Extraction Procedure: Reproducibility and Sensitivity, EPRI, November 1, 1979.(37)
- Evaluation of Procedures for Identification of Hazardous Waste, Interim Report, EMSL-LV (18)
- Background Study on Development of Standard Leaching Test (EPA-600/2-79-107)(14)

Approximately 30 comments were received in response to the Agency's notice of these reports. In the main the comments did not address themselves to the specific scientific results reported in these studies. Rather they addressed their interpretation of the meaning of the work in relation to the proposed toxicity definition as enunciated in the EP Toxicity characteristic and the criteria for delisting.(9)

While the comments dealt with a number of issues, most of these have been discussed previously in this background document. This section will address the remaining issues as well as clarify several points made by commenters who had apparently not availed themselves of the explanatory material made available in the draft Toxicity Background Document(6) and thus were not aware of the intent and rationale behind the work done during these studies.

Comment: No factual basis for defining hazard has been developed in these studies and no recognized standard of judgment has been applied to this work.

Response: The basis for the Extraction Procedure developed as a result of these studies has been described previously in this document. The basis for the bioassay tests has been discussed in the aforementioned draft Background Document.(6) The reason different dilutions of the EP extract were examined for toxic effects in the various bioassays relates to the fact that the model of environmental exposure used in developing the EP Toxicity characteristic postulates different degrees of dilution for different targets of exposure (e.g., fish, plants). Chronicly toxic effects toward the aquatic and terrestrial plant environments were thus studied at the expected levels of exposure. The organisms employed in these studies were believed to be sensitive enough for such an approach to be used.

Comment: "CMA recognizes that an uncomplicated short-term test is necessary for initial screening of the large body of wastes to define potential hazard. The single elution, solid/liquid ratio, and the time per elution of the proposed EPA are a practical compromise to more complex procedures such as the SLT reviewed in the subject document. The setting of a threshold concentration as the basis for defining hazard makes proper use of the most important data such tests develop".

Response: The Agency appreciates the fact that these commenters took the time to let EPA know they concur with our conclusion.

Comment: Work done by ASTM under Phase II of a study supported by the U.S. Department of Energy indicated that the EP is not reproducible.

Response: The Agency is aware of this study but has been unable to obtain a copy of the results from the sponsoring ASTM subcommittee. Thus, the results of this work have not been included in the data base used to develop the EP characteristic.

Comment: The quality of the work performed at ORNL is suspect since less than adequate quality assurance procedures were employed.

Response: The Agency believes the work performed at ORNL(7,9) to be scientifically valid pending any specific evidence to the contrary.

Comment: The EP is not reproducible.

Response: While this point was raised in a number of comments, the comments by two groups, the American Petroleum Institute (API) and the Utility Solid Waste Activities Group (USWAG) were the most specific and detailed and thus have been specifically addressed.

In general, the Agency agrees with many of the criticisms noted in the API and USWAG comments relative to the incompleteness of the data base, and its ability to precisely define the reproducibility of the EP and analytical procedures. However, as with the studies themselves, the commenters often do not clearly distinguish in their comments between reproducibility as it relates to the EP or as it relates to the analytic techniques. Also, there appears to be some expectation that the EP and analytic techniques should have similar reproducibility

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indicators for each of the eight elements and for each of many different waste types. This may represent a fundamental misconception about the reproducibility of both the EP and the analytic techniques. This expectation is somewhat similar to expecting that a test battery that measures vastly different types of abilities should have an overall reliability estimate that applies equally to all age groups. Further, as in the studies themselves, the comments do not indicate what would be an acceptable level of reproducibility. Failure to provide some guidelines of what general levels of reproducibility would be acceptable for the EP and the analysis techniques tends to compromise the criticisms offered. The critical issue is whether the proposed EPA guidelines and regulations regarding the EP and analysis techniques have adequate reproducibility to serve as a screening mechanism for identifying potentially hazardous wastes. It should be borne in mind that since the Agency has raised the definitional threshold to 100 times the applicable NIPDWS threshold, many of the criticisms made by the commenters do not apply. This is due to the fact that at higher thresholds the toxicants are analytically easier to measure and the percent error would be expected to decrease significantly.

API Comments

The API comments concern a review and discussion of the results of the four studies (18,35,36,37) conducted on the reproducibility of the EP and AA analysis techniques. The

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four separate studies were conducted by Electric Power Research Institute (EPRI),(37) NUS Corporation (36), the American Electroplater's Society (AES)(35) and the EPA Environmental Monitoring Systems Laboratory,(18) respectively.

Comments on the NUS study (36) tend to misinterpret the relative standard error (RSE) used by the NUS investigators as an index of reproducibility. For example the comments include the statement that the standard error which defines the distribution of the means is related to the standard deviation (36, p.4). This is true, but the standard error (of the mean) is also a function of the number of analytic replications, an important component in determining the size of the standard error (of the mean). In this regard, the comments state that "API would hesitate to accept any procedure with such a high analytical error" (± 30% RSE) (36, p.4). With a ± 1 RSE representing the 95% confidence interval about the mean value of lead in BOF slag, one wonders what RSE would be acceptable to API.

The Agency generally agrees that the NUS report is not a thorough study and is incomprehensible (36, p.5) but cannot agree that levels of toxic metals below detection limits should be reported as 0.000 ppm and included in the analysis (36, p. 5). EPA believes that values at or near the limit of detection and which are orders of magnitude below the threshold levels should not be included in reproducibility estimates, only those levels near the threshold values or above should be included.

Comments regarding the EP and Toxic Extraction Procedure (TEP) comparisons in the API Comments are irrelevent since the EPA regulations specify only the use of the EP.

API comments on the EPRI report(37) seem valid generally, except that the comments regarding the Confidence Multipliers (CMs) in the EPRI report tend to ignore the study limitations noted by the authors of the EPRI report. Many of the extreme confidence intervals include analyses which the authors of the EPRI study note should be interpreted with caution (because of variability due to unallocated error or because the number of values below detection units are large enough to make the results less reliable) (p. 3 of Phase I report).(37) Also, reporting extreme 90% confidence limits as percentage of the mean is a somewhat misleading way to present reproducibility data. The percentages reflect both measurement error and 90% of the area included under a normal distribution.

API comments on the study by the EPA Environmental Monitoring Systems Laboratory (EMSL)(18) in Las Vegas tend to be confusing. For example, ICP was used as a screening device by EMSL to determine what wastes would be subjected to the EP and the AA analyses. The API comments, however, discuss the ICP results as though they were indicators of the EP and analytical reproducibilities. Specifically, the API comments state that the ICP analysis results indicate there is something amiss with the EP or analytical procedure. The ICP has nothing to do with EP reproducibility. Also, the EMSL is criticized by API for being incomplete even though the report(18) is clearly indicated as an interim report and includes statements about further analyses that are planned.

API comments on the AES study(35) intersperse comments on the design of AES experiments with issues relating to the reproducibility of the EP and analytic techniques. For example, in the AES experiment with different levels of pH used for the EPA, the unreproducibility of the EP at the standard pH 5 levels is not established simply because different analytical results were obtained at other pH levels. Even so, the analytic results at pH 5 seemed somewhat more uniform than the analytic results at the other pH levels. As indicated earlier, the API comment regarding the overall reliability of the EP may reflect a misconception that the EP should be equally reproducible for all types of solid wastes.

USWAG Comments

The comments submitted by the Utility Solid Waste Activities Group (USWAG) tend to be more focussed through the API comments upon the specific research results of three studies regarding the reproducibility of the EP and AA analytic methods. In general, the review by USWAG consultants, Envirosphere, submitted along with the comments is a fairly thorough evaluation of the methodological and scientific merits of each of three studies, the EPRI study,(37) the EPA EMSL study,(18) and the NUS Corporation study.(36) The USWAG comments regarding the variability of analytic results according to the types of wastes and toxic metals examined tends to be supported across the different studies. However, as indicated earlier, reproducibility estimates need to be established for each type of waste and for each elemental analysis.

The USWAG comment regarding the appropriateness of the use of any standardized leaching test to "perform more than an initial screening function" is somewhat confusing. The EP and analytic techniques coupled with the threshold levels serve as a screening mechanism for determining wastes requiring controlled management. The accuracy of the EP and analytic techniques to model actual leaching at specific disposal sites will not be established until studies comparing the model results with actual disposal site leaching are conducted. As was discussed previously, the EP is not meant to model any specific disposal site but is instead a generalized model.

As with the API comments, the measures of the relative standard error used in the NUS report(36) tends to be interpreted as a relative standard deviation (RSD) or coefficients of variability in the USWAG comments. Also, the USWAG comments on the EPRI report(37) include most of the Confidence Multiplier (CMs) for each element included in the EPRI report. If, for example, one only includes those data which are largely complete for the ANOVA design, a somewhat different picture emerges of the reproducibility of intra-laboratory analyses (consistency) and inter-laboratory analyses (concurrence). The following distributions of CMs are found with a more conservative extraction of the EPRI data (37, p. 14) (indicators of inter- and intra-laboratory reproducibility on the combined AA analysis results).

	Inter-Laboratory Analysis CMs		Intra-Laboratory Analysis CMs	
Intervals	N	%	N	%
1.01-1.25	13	52	20	80
1.26-1.50	0	0	4	16
1.51-1.75	1	4	1	4
1.76-2.00	2	8	0	0
2.01-2.25	1	4	0	0
2.26-2.50	0	0	0	0
2.51 +	8	32	0	0
Totals	25	100%	25	100%

These results suggest that the reproducibilities of intra-laboratory analysis techniques (consistency) are appreciably better than inter-laboratory analysis reproducibilities (concurrence). A different (and less positive) picture emerges when all the data results are considered as in the API comments and the USWAG comments. Also, averaging all the CMs presented in the EPRI study(37) tends to present an inflated picture of the CMs, since the mean is affected by extreme values and the extreme values are very large CMs. The USWAG comments regarding the NUS report,(36) however, seem justified, except that RSEs are reported as relative standard deviations (same as coefficients of variation).

The report attached to the USWAG comments, completed by the Environsphere Company, is a thorough and insightful review of the three reproducibility studies. However, the Agency questions the inclusion of sampling techniques as part of determining reproducibilities in the "Toxic Waste Test." It is generally understood that the EPA guidelines regarding sampling techniques for solid waste need further refinement. At the present time, the precision and reproducibility of the EP and AA techniques is the central issue. Also, presentation of the "corrected mean concentrations" of elements from the EPRI report (37, pp. 17-19) does not adequately reflect reproducibilities of the analytic procedures, since these values incorporate variances attributable to both the EP and to the analytic technique.

The consultant's report addresses the issues of the incorrect statistical summaries presented in Table 8 of the EMSL(18) report, yet fails to point out that their corrected values indicate an increased reproducibility estimate for the pH levels and percent solid determinations. Also, the Agency cannot understand why, in both the EMSL(18) study and the consultants review, ANOVA techniques were used without multiple comparisons tests. A simple t-test between the highest and lowest mean values for chromium in Pond P, 2A, and lead in Pond O, 2B, did not indicate significant differences within three replicate analyses of the same samples. The consultants are not particularly clear about how they conducted their own ANOVAs analyses.

Comment: Specification of construction materials for extractor must be flexible in order to accomodate different waste materials.

Response: Neither the proposed nor final regulations specify materials of construction for the extraction equipment. The Agency agrees that those evaluating waste materials should use materials of construction appropriate to the properties of the waste and to the analyses to be conducted.

Comment: None of the reports evaluated analytical procedures for the pesticides.

Response: Due to the unavailability to the Agency of wastes containing significant concentrations of pesticides, these were not included in the test program. However, no comments were received indicating problems in analyzing EP extracts for pesticides.

Comment: Neither vacuum filtration nor mechanical agitation are appropriate for determining if wastes contain volatile materials.

Response: The Agency agrees and is not using the EP to determine if a waste poses a potential hazard due to its content of volatile compounds.

Comment: Concentrating extracts prior to analysis is inappropriate since it does not simulate what happens in the real world.

Response: The commenter appears to misunderstand the intent of the concentration step. The purpose of concentrating the extract prior to analysis is to improve the accuracy of the analytical determination. Thresholds for toxicity are expressed on the basis of concentration in the original extract. Concentrating the extract prior to analysis does not change the measure of toxicity.

Comment: The fact that a sample of sewage sludge failed the proposed criteria for cadmium and mercury indicates the excessive severity of the EP.

Response: The Agency disagrees with this comment. Many municipal sewage sludges contain concentrations of cadmium and other metals sufficient to pose a health hazard if improperly used for soil amendment or fertilization use. Thus these sludges would be hazardous wastes under RCRA. However, using the thresholds promulgated today (i.e., 100X NIPDWS), none of the municipal wastes tested would have met the definition of hazardous waste.

Comment: Use of the resin technique for concentrating organic materials present in the extract as part of the analytical procedures is not suitable for all types of organic compounds.

Response: The Agency agrees with this comment. However, this technique is currently under evaluation and has not been included in the regulations promulgated today.

Comment: The meaning of the results using the arsenic contaminated groundwater is in question given the unknown handling and storage of the sample.

Response: The groundwater sample was not employed to determine if any specific waste was a hazardous waste, but rather served as an investigatory tool. Thus, irrespective of its history, since its composition prior to biological use was determined, the results obtained are valid.

A number of comments were received relative to biological test procedures which had been proposed as part of the delisting procedures under Part 250.15. Since these test procedures have not been included in the regulation promulgated today, a detailed discussion of these comments will not be included in this discussion. In general, the Agency agrees with the commenters who indicated that the EP extractant liquid seriously interfered with the phytotoxicity test procedure. However, the Agency believes that this problem with the EP extractant fluid does not apply to either the mutagenicity or _Daphnia_ _magna_ chronic toxicity assays. As has been discussed previously in this Background Document, the Agency does not believe, however, that these assays are ready for general use by the regulated community.

VI. PROMULGATED REGULATION

§261.24 Characteristic of EP Toxicity

(a) A solid waste exhibits the characteristic of EP toxicity if, using the test methods described in Appendix II or equivalent methods approved by the Administrator under the procedures set forth in §§260.20 and 260.21, the extract from a representative sample of the waste contains any of the contaminants listed in Table I at a concentration equal to or greater than the respective value given in that Table. Where the waste contains less than 0.5 percent filterable solids, the waste itself, after filtering, is considered to be the extract for the purposes of this section.

(b) A solid waste that exhibits the characteristic of EP toxicity, but is not listed as a hazardous waste in Subpart D, has the EPA Hazardous Waste Number specified in Table I which corresponds to the toxic contaminant causing it to be hazardous.

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Table I

Maximum Concentration of Contaminants for Characteristic of EP Toxicity

EPA Hazardous Waste Number	Contaminant	Maximum Concentration (milligrams per lite)
D004	Arsenic	5.0
D005	Barium	100.0
D006	Cadmium	1.0
D007	Chromium	5.0
D008	Lead	5.0
D009	Mercury	0.2
D010	Selenium	1.0
D011	Silver	5.0
D012	Endrin (1,2,3,4,10,10-hexachloro-1 7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1 4-endo, endo-5,8-dimethano naphthalene	0.02
D013	Lindane (1,2,3,4,5,6-hexachlorocyclohexane, gamma isomer	0.4
D014	Methoxychlor (1,1,1-Trichloro-2,2-bis [p-methoxyphenyl]ethane)	10.0
D015	Toxaphene ($C_{10}H_{10}Cl_8$, Technical chlorinated camphene, 67-69 percent chlorine)	0.5
D016	2,4-D, (2,4-Dichlorophenoxyacetic acid)	10.0
D017	2,4,5-TP Silvex (2,4,5-Trichlorophenoxypropionic acid)	1.0

APPENDIX II

EP Toxicity Test Procedure

A. Extraction Procedure (EP)

1. A representative sample of the waste to be tested (minimum size 100 grams) should be obtained using the methods specified in Appendix I or any other method capable of yielding a representative sample within the meaning of Part 260. [For detailed guidance on conducting the various aspects of the EP see "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods," SW-846, U.S. Environmental Protection Agency Office of Solid Waste, Washington, D.C. 20460.*]

2. The sample should be separated into its component liquid and solid phases using the method described in "Separation Procedure" below. If the solid residue** obtained using this method totals less than 0.5% of the original weight of the waste, the residue can be discarded and the operator should treat the liquid phase as the extract and proceed immediately to Step 8.

3. The solid material obtained from the Separation Procedure should be evaluated for its particle size. If the solid material has a surface area per gram of material

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* Copies may be obtained from Solid Waste Information, U.S. Environmental Protection Agency, 26 W. St. Clair Street, Cincinnati, Ohio 45268

**The percent solids is determined by drying the filter pad at 80°C until it reaches constant weight and then calculating the percent solids using the following equation:

$$\frac{(\text{weight of pad + solid}) - (\text{tare weight of pad})}{\text{initial weight of sample}} \times 100 = \%\ \text{solids}$$

equal to, or greater than, 3.1 cm^2 or passes through a 9.5 mm (0.375 inch) standard sieve, the operator should proceed to Step 4. If the surface area is smaller or the particle size larger than specified above, the solid material should be prepared for extraction by crushing, cutting or grinding the material so that it passes through a 9.5 mm (0.375 inch) sieve or, if the material is in a single piece, by subjecting the material to the "Structural Integrity Procedure" described below.

4. The solid material obtained in Step 3 should be weighed and placed in an extractor with 16 times its weight of deionized water. Do not allow the material to dry prior to weighing. For purposes of this test, an acceptable extractor is one which will impart sufficient agitation to the mixture to not only prevent stratification of the sample and extraction fluid but also insure that all sample surfaces are continuously brought into contact with well mixed extraction fluid.

5. After the solid material and deionized water are placed in the extractor, the operator should begin agitation and measure the pH of the solution in the extractor. If the pH is greater than 5.0, the pH of the solution should be decreased to 5.0 ± 0.2 by adding 0.5 N acetic acid. If the pH is equal to or less than 5.0, no acetic acid should be added. The pH of the solution should be monitored, as described below, during the course of the extraction and if

the pH rises above 5.2, 0.5N acetic acid should be added to bring the pH down to 5.0 ± 0.2. However, in no event shall the aggregate amount of acid added to the solution exceed 4 ml of acid per gram of solid. The mixture should be agitated for 24 hours and maintained at 20° - 40°C (68°-104°F) during this time. It is recommended that the operator monitor and adjust the pH during the course of the extraction with a device such as the Type 45-A pH Controller manufactured by Chemtrix, Inc., Hillsboro, Oregon 97123 or its equivalent, in conjunction with a metering pump and reservoir of 0.5N acetic acid. If such a system is not available, the following manual procedure shall be employed:

(a) A pH meter should be calibrated in accordance with the manufacturer's specifications.

(b) The pH of the solution should be checked and, if necessary, 0.5N acetic acid should be manually added to the extractor until the pH reaches 5.0 ± 0.2. The pH of the solution should be adjusted at 15, 30 and 60 minute intervals, moving to the next longer interval if the pH does not have to be adjusted more than 0.5N pH units.

(c) The adjustment procedure should be continued for at least 6 hours.

(d) If at the end of the 24-hour extraction period, the pH of the solution is not below 5.2 and the maximum amount of acid (4 ml per gram of solids) has not been added, the pH should be adjusted to 5.0 ± 0.2 and the extraction continued for an additional four hours, during which the pH should be adjusted at one hour intervals.

6. At the end of the 24 hour extraction period, deionized water should be added to the extractor in an amount determined

by the following equation:

$V = (20)(W) - 16(W) - A$

V= ml deionized water to be added

W= weight in grams of solid charged to extractor

A= ml of 0.5N acetic acid added during extraction

7. The material in the extractor should be separated into it component liquid and solid phases as described under "Separation Procedure."

8. The liquids resulting from Steps 2 and 7 should be combined. This combined liquid (or the waste itself if it has less than 1/2 percent solids, as noted in step 2) is the extract and should be analyzed for the presence of any of the contaminants specified in Table I of §261.24 using the Analytical Procedures designated below.

Separation Procedure

Equipment: A filter holder, designed for filtration media having a nominal pore size of 0.45 micrometers and capable of applying a 5.3 kg/cm^2 (75 psi) hydrostatic pressure to the solution being filtered shall be used. For mixtures containing nonabsorptive solids, where separation can be affected without imposing a 5.3 kg/cm^2 pressure differential, vacuum filters employing a 0.45 micrometrers filter media can be used. (For further guidance on filtration equipment or procedures see "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.")

Procedure:*

(i) Following manufacturer's directions, the filter unit should be assembled with a filter bed consisting of a 0.45 micrometer filter membrane. For difficult or slow to filter mixtures a prefilter bed consisting of the following prefilters in increasing pore size (0.65 micrometer membrane, fine glass fiber prefilter, and coarse glass fiber prefilter) can be used.

(ii) The waste should be poured into the filtration unit.

(iii) The reservoir should be slowly pressurized until liquid begins to flow from the filtrate outlet at which point the pressure in the filter should be immediately lowered to 10-15 psig. Filtration should be continued until liquid flow ceases.

(iv) The pressure should be increased stepwise in 10 psi increments to 75 psig and filtration continued until flow ceases or the pressurizing gas begins to exit from the filtrate outlet.

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*This procedure is intended to result in separation of the "free" liquid portion of the waste from any solid matter having a particle size >0.45um. If the sample will not filter, various other separation techniques can be used to aid in the filtration. As described above, pressure filtration is employed to speed up the filtration process. This does not alter the nature of the separation. If liquid does not separate during filtration, the waste can be centrifuged. If separation occurs during centrifugation, the liquid portion (centrifugate) is filtered through the 0.45um filter prior to becoming mixed with the liquid portion of the waste obtained from the initial filtration. Any material that will not pass through the filter after centrifugation is considered a solid and is extracted.

(v) The filter unit should be depressurized, the solid material removed and weighed and then transferred to the extraction apparatus, or, in the case of final filtration prior to analysis, discarded. Do not allow the material retained on the filter pad to dry prior to weighing.

(vi) The liquid phase should be stored at 4°C for subsequent use in Step 8.

B. Structural Intergrity Procedure

Equipment: A Structural Integrity Tester having a 3.18 cm (1.25 in.) diameter hammer weighing 0.33 kg (0.73 lbs.) and having a free fall of 15.24 cm (6 in.) shall be used. This device is available from Associated Design and Manufacturing Company, Alexandria, VA., 22314, as Part No. 125, or it may be fabricated to meet the specifications shown in Figure 1.

Procedure:

1. The sample holder should be filled with the material to be tested. If the sample of waste is a large monolithic block, a portion should be cut from the block having the dimensions of a 3.3 cm (1.3 in.) diameter x 7.1 cm (2.8 in.) cylinder. For a fixated waste, samples may be cast in the form of a 3.3 cm (1.3 in.) diameter x 7.1 cm (2.8 in.) cylinder for purposes of conducting this test. In such cases, the waste may be allowed to cure for 30 days prior to further testing.

2. The sample holder should be placed into the Structural Integrity Tester, then the hammer should be raised

to its maximum height and dropped. This should be repeated fifteen times.

3. The material should be removed from the sample holder, weighed, and transferred to the extraction apparatus for extraction.

Analytical Procedures for Analyzing Extract Contaminants

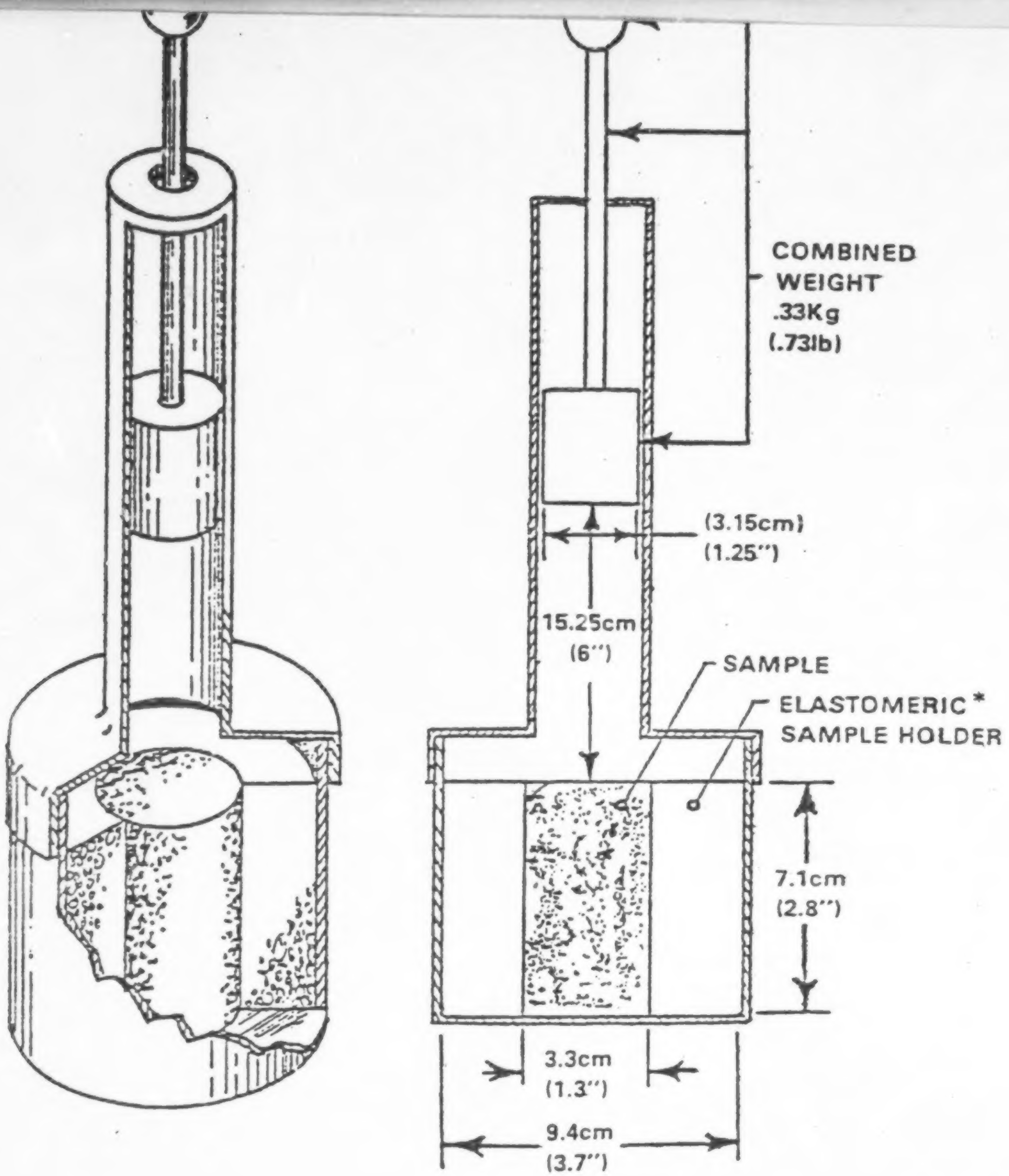
The test methods for analyzing the extract are as follows:

(1) For arsenic, barium, cadmium, chromium, lead, mercury, selenium or silver: "Methods for Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (EPA-600/4-79-020, March 1979).

(2) For Endrin; Lindane; Methoxychlor; Toxaphene; 2,4-D; 2,4,5-TP Silver: in "Methods for Benzidine, Chlorinated Organic Compounds, Pentachlorophenol and Pesticides in Water and Wastewater," September 1978, U.S. Environmental Protection Agency, Environmental Monitoring and Support Laboratory, Cincinnati, Ohio 42568.

as standardized in "Test Methods for the Evaluation of Solid Waste, Physical/Chemical Methods."

For all analyses, the method of standard addition shall be used for the quantification of species concentration. This method is described in "Test Methods for the Evaluation of Solid Waste." (It is also described in "Methods for Analysis of Water and Wastes.")


COMBINED WEIGHT
.33Kg
(.73lb)
(3.15cm)
(1.25")
15.25cm
(6")
SAMPLE
ELASTOMERIC*
SAMPLE HOLDER
7.1cm
(2.8")
3.3cm
(1.3")
9.4cm
(3.7")

*ELASTOMERIC SAMPLE HOLDER FABRICATED OF MATERIAL FIRM ENOUGH TO SUPPORT THE SAMPLE

Figure 1

COMPACTION TESTER

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